Comparative study of Fatty meal vs Drotaverine Hydrochloride vs Hyoscine-N-butylbromide for Duodenal Antimotility and Ease of cannulation during Endoscopic Retrograde Cholangiopancreatography (ERCP)

Dissertation Submitted

to

THE TAMILNADU DR. M.G.R. MEDICAL UNIVERSITY

For

D.M. Degree in Medical Gastroenterology

BRANCH-IV

CHENNAI

AUGUST 2014

DEPARTMENT OF MEDICAL GASTROENTEROLOGY

MADRAS MEDICAL COLLEGE & HOSPITAL

CHENNAI-03

CERTIFICATE

This is to certify that the dissertation entitled **"Comparative study of Fatty meal versus Drotaverine Hydrochloride versus Hyoscine-N-Butylbromide for Duodenal Antimotility and ease of cannulation During Endoscopic Retrograde Cholangiopancreatography (ERCP)",** is a bonafide work done by **Dr.VADIVEL KUMARAN.S.,** Post-Graduate in Medical Gastroenterology, Madras Medical College, in partial fulfillment of the university rules and regulations for award of "**D.M. IN MEDICAL GASTROENTEROLOGY"** under my guidance and supervision during the academic year June 2013 to March 2014.

Professor Dr.T.Pugazhendhi
Addl.Prof. and Guide/Unit Chief
Department of Medical Gastroenterology
Madras Medical College & Hospital
Chennai-03

Prof. Dr.Mohammed Ali
Prof. and HOD
Department of Medical Gastroenterology
Madras Medical College & Hospital
Chennai-03

Prof.R.Vimala,M.D
DEAN
Madras Medical College & Hospital
Chennai-03

DECLARATION

I solemnly declare that the Dissertation titled "***Comparative study of Fatty meal vs Drotaverine Hydrochloride vs Hyoscine-N-butylbromide for Duodenal Antimotility and ease of cannulation During Endoscopic Retrograde Cholangiopancreatography (ERCP)*",** was done by me at Madras Medical College & Hospital during the period from June 2013 to March 2014, under the guidance and supervision of Prof. Dr.T.Pugazhendhi and Prof.Dr.Mohammed Ali

This dissertation is submitted to The Tamilnadu Dr. *M.G.R.* Medical University towards the partial fulfillment of the requirement for the award of D.M. Degree (Branch *IV*) in Medical Gastroenterology.

Place : Chennai

Date :

Dr.VADIVEL KUMARAN.S.

Department of Medical Gastroenterology
Madras Medical College & Hospital
Chennai-03

ACKNOWLEDGEMENT

I sincerely thank **Dr.R.VIMALA, M.D.,** Dean-Madras Medical College and Hospital, Chennai and former Dean **Dr.V.KANAGASABAI, M.D.,** for having permitted me to undertake the study in this prestigious institution.

It is a great pleasure to express my sincere thanks to **Prof.Dr.MOHAMMED ALI,M.D.,D.M.,** Head of the Department of Medical Gastroenterology & my Unit Chief **Prof.Dr.T.PUGAZHENDHI,M.D.,D.M.,** Madras Medical College and Hospital, Chennai for his able stewardship in the preparation of this work.

I whole heartedly thank all my unit Assistant Professors viz. **Dr.K.PREM KUMAR,M.D.,D.M., Dr.P.RATNAKAR KINI,M.D.,D.M., Dr.KANI SHAIKH MOHAMMED,M.D.,D.M.,** for their professional assistance in shaping out this dissertation work.

S.No. CONTENTS PAGE No.

INTRODUCTION

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is in clinical practice since 1968 for diagnosis and treatment of pancreatobiliary diseases[1]. ERCP is a technically demanding procedure that requires considerable amount of training to be performed safely[2]. Common bile duct (CBD) and/or the pancreatic duct (PD) cannulation is the critical step. Failed intervention or an aborted procedure is due to failure of cannulation of the desired ducts.

A side viewing duodenoscope of 120cms is necessary for cannulation of normal gastrointestinal anatomy, whereas a forward viewing duodenoscope may be necessary in case of altered anatomy like Billroth II anastomoses, Roux-en Y anastomosis, Choledochojejunostomy and Hepaticojejunostomy. In surgically altered anatomy, usage of a double or "short" double-balloon and single balloon enteroscopy has achieved a higher successful cannulation rates. For diagnostic and therapeutic interventions like sphincterotomy, stent placement and stone extraction, cannulation of the ampulla of Vater and wire access of the ampulla is the prime requirement.

A higher rate of successful cannulation without complications usually depends on the expertise of the endoscopist. Those with lesser experience have a much lower rate of success and higher occurrence of complications. The anatomy typically predisposes to pancreatic duct cannulation as the pancreatic duct enters the ampulla in a straight fashion[3]. Edema or strictures in the small bowel, surgically altered anatomy, blood or excessive fluid in the lumen and periampullary diverticulum increases the difficulty of the procedure. Prolonged cannulation often results in increased patient morbidity, unnecessary radiation exposure and anxiety for endoscopists[4]. With normal anatomy, various technical methods have been adopted to facilitate cannulation at ERCP based on technical and pharmacological aspects.

Technical methods:

Standard techniques-

- Catheters
- Papillotomes
- Guide wires in conjunction with catheters and papillotomes
- Placement of pancreatic stent or guide wire to facilitate cannulation

Precut techniques-

- Precut papillotomy (needle knife papillotomy)

- Transpapillary pancreatic sphincterotomy (precut pancreatic sphincterotomy)
- Suprapapillary puncture of the common bile duct (needle knife fistulotomy)

Endoscopic ultrasound-guided cholangiography

Pharmacologic methods:

Major papilla	*Minor papilla*
Intravenous injection of CCK	Intravenous injection of Secretin
Topical nitroglycerin	Topical Methylene blue
Fatty meal before ERCP	Intraduodenal acid infusion

Difficult cannulation, multiple attempts at cannulation and multiple pancreatic duct injections increases the risk of post-ERCP pancreatitis[5,6]. Prolonged cannulation attempt leads to edema, papillary trauma, inability to achieve deep ductal access, bleeding and is often associated with significant adverse events such as perforation and pancreatitis[7,8]. Hence, quick and atraumatic biliary cannulation is essential for a successful ERCP.

Conventionally, cannulation is facilitated with the help of Hyoscine-N-butyl bromide or Drotaverine, smooth muscle relaxants to impair duodenal contractions and sphincter of oddi relaxation. Barrie M et al has showed that before ERCP, the administration of a liquid fatty meal facilitates biliary cannulation, by relaxing the sphincter of Oddi (SO)[9]. In this study we have compared the efficacy of Hyoscine-N-butyl bromide, Drotaverine and fatty meal in the ease of identification of ampulla, ease of cannulation, time for cannulation, hemodynamic changes and adverse effects of the drugs used.

AIM OF THE STUDY

AIM

To compare the effect of Fatty meal versus Drotaverine hydrochloride versus Hyoscine-N-butyl bromide:

- On duodenal contraction rate
- To identify the ampulla
- Time for cannulation
- Adverse events

Primary Outcome Measures:

To Grade the Number of Duodenal Contractions during the procedure:

Duodenal motility grade-

0	no motility
1	< 5/min
2	5 - 10/min
3	11 - 15/min
4	Persistent

Secondary Outcome Measures-

Cannulation Time

Percentage of Successful Selective Cannulation

Adverse effects of drugs

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Endoscopic retrograde cholangiopancreatography (ERCP) is more often utilized for therapeutic procedures with the advent of magnetic resonance cholangiopancretogram (MRCP)[10,11]. Cannulation of the bile duct or the pancreatic duct through the ampulla requires adequate expertise and a roadmap of the hepatobiliary ducts by non-invasive imaging studies. A normal gastrointestinal and hepatobiliary anatomy favors the cannulation of the pancreatic duct.

The ampullary eminence is produced by a mucous membrane bulge, called the duodenal papilla. The pancreatic and bile duct separately opens into the duodenum, in 10% to 15% of patients[12].

With the Patient in prone or left lateral decubitus position the side viewing duodenoscope is intubated and positioned in second part of duodenum. The major papilla is identified by the presence of a papillary orifice, a hood, a frenulum and an infundibulum in the second part of the duodenum (Fig.1). The minor papilla is located 2 cm proximal and anterior to the major papilla and is smaller.

AMPULLA CANNULATION:

Prior to the procedure the catheter or sphincterotome is flushed with saline or contrast agent to prevent injection of air into the ducts during cannulation attempt or a guide-wire is placed up-to the tip.

For selective bile duct cannulation the side-viewing duodenoscope is placed below the major papilla. The catheter is positioned below the major papilla and directed vertically towards the 11-12 o'clock position.

For selective pancreatic duct cannulation the side-viewing duodenoscope is positioned en-face and slightly to the left of the papilla. The catheter is placed onto the right of the papilla between 1and 3 o'clock position and moved from left to right. Then it is advanced deep into the duct.

For minor papilla cannulation the patient is positioned supine with the long scope position. The Os is small (2mm) running from 5 o'clock to the 11 o'clock position. It is first cannulated with wire followed by the sphincterotome.

THE SPHINCTER AND THE BILE DUCT:

The bile duct is approximately 7 cm long[12]. The common bile duct averages 0.5 to 1.5 cm in diameter[13]. The bile duct takes an oblique course through the postero-medial aspect of the wall of the duodenum to form the ampulla of Vater after joining the main pancreatic duct (Fig.2)[14].

Sphincter of Oddi (Fig.3) is usually composed of:

- The sphincter choledochus
- The sphincter pancreaticus

NORMAL PAPILLA

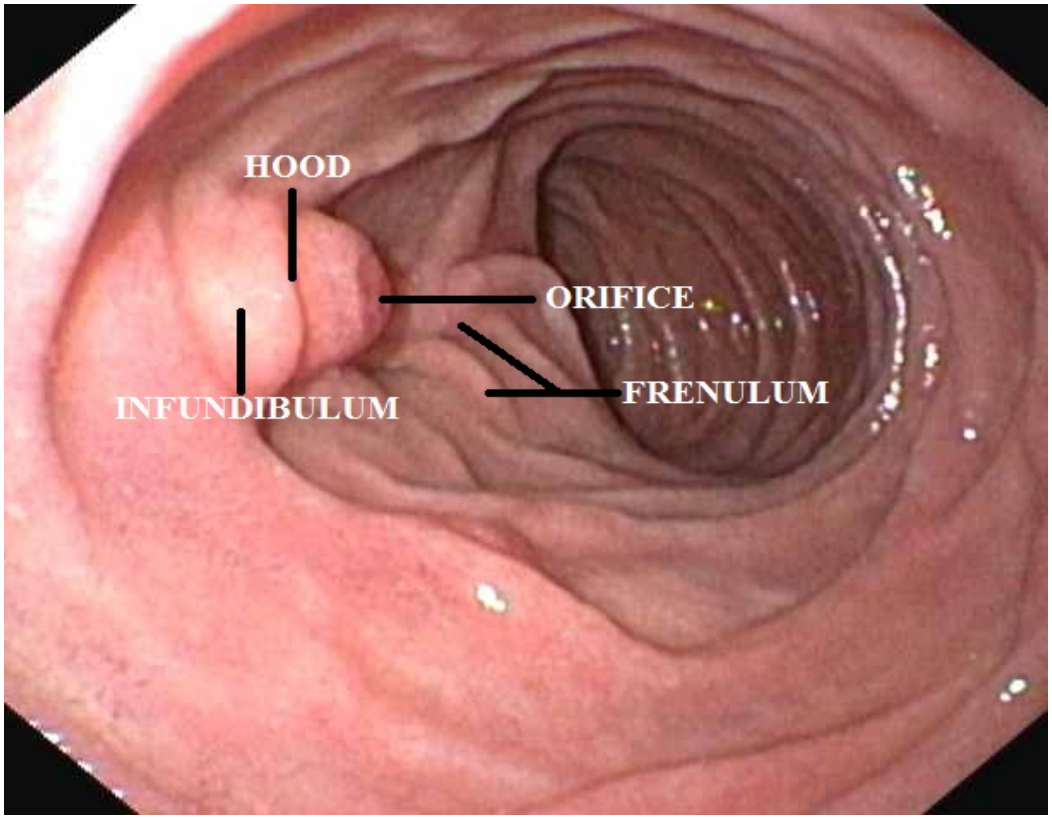


Fig.1

EXTRAHEPATIC BILE DUCTS

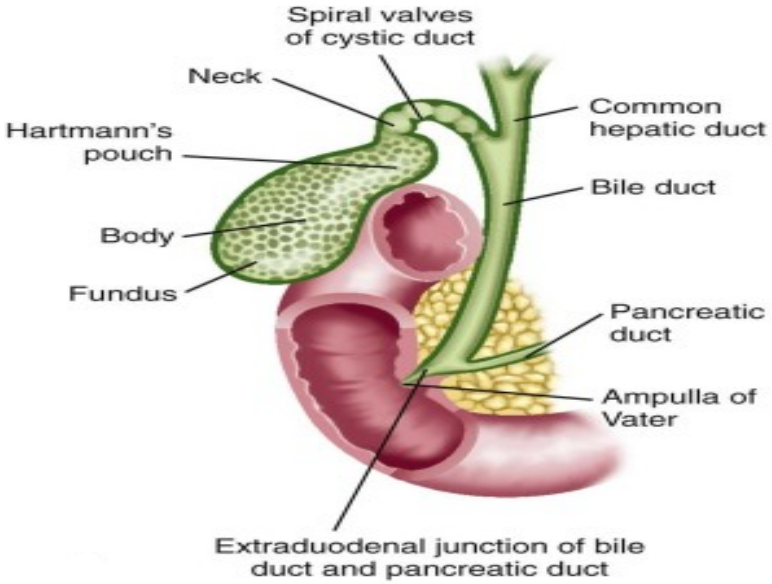


Fig.2

- The fasciculi longitudinales
- The sphincter ampullae

The circular muscle fiber surrounding the intramural part of the bile duct, before its junction with the pancreatic duct, is sphincter choledochus. The circular muscle fibers surrounding the intraduodenal part of the pancreatic duct before its junction with the ampulla, is sphincter pancreaticus. The longitudinal muscle bundles between the pancreatic and bile ducts, is fasciculi longitudinales. The sphincter ampulla is a sparse layer of circular fibers surrounded by longitudinal muscle fibers, around the ampulla of Vater[15]. The bile duct and pancreatic duct end in the ampulla. Reflux of bile into the pancreatic duct may be caused by the contraction of the sphincter[16].

THE PANCREATIC DUCT:

The main pancreatic duct and the bile duct joins to reach the duodenal papilla, at the level of pancreatic head (Fig.4). The ducts may have an interposed septum or may have a common channel to open into the ampulla or open separately. The common channel length varies between 1 to 12 mm, averaging 4.5 mm[17,18]. The accessory pancreatic duct of Santorini communicates with the main duct. It drains into the minor papilla, 2cm proximal to the ampulla after running anterior to the bile duct.

ORGANISATION OF THE SMALL INTESTINE:

The small intestine has four layers: the mucosa, the submucosa, the muscularis, and the serosa, from the lumen outward. Smooth muscle fibers are seen in the submucosa (muscularis mucosae) and two layers of smooth muscle in the muscularis mucosa, an outer longitudinal and an inner circular layer.

Two major networks of nerve fibers, the myenteric plexus (Auerbach's plexus) and the submucous plexus (Meissner's plexus) constitutes the enteric nervous system. The myenteric plexus innervates the outer longitudinal and the inner circular smooth muscle layers and is the primary with motor control. The submucosal plexus innervates the glandular epithelium, intestinal endocrine cells and submucosal blood vessels. It controls the intestinal secretion. The neurotransmitters in the system include acetylcholine, norepinephrine, serotonin and the amino acid GABA.

The basic electrical rhythm (BER) is the spontaneous rhythmic fluctuations in membrane potential of the gastrointestinal smooth muscles. It is initiated by the interstitial cells of Cajal, situated in the outer circular muscle layer near the myenteric plexus. There is a descending gradient in pacemaker frequency, down the small intestine. It is about 12/min in the duodenum, falling to about 8/min in the distal ileum. The function of the BER is to coordinate peristaltic and other motor activity but contractions occur only during the depolarizing part of the waves.

ANATOMY OF SPHINCTER OF ODDI

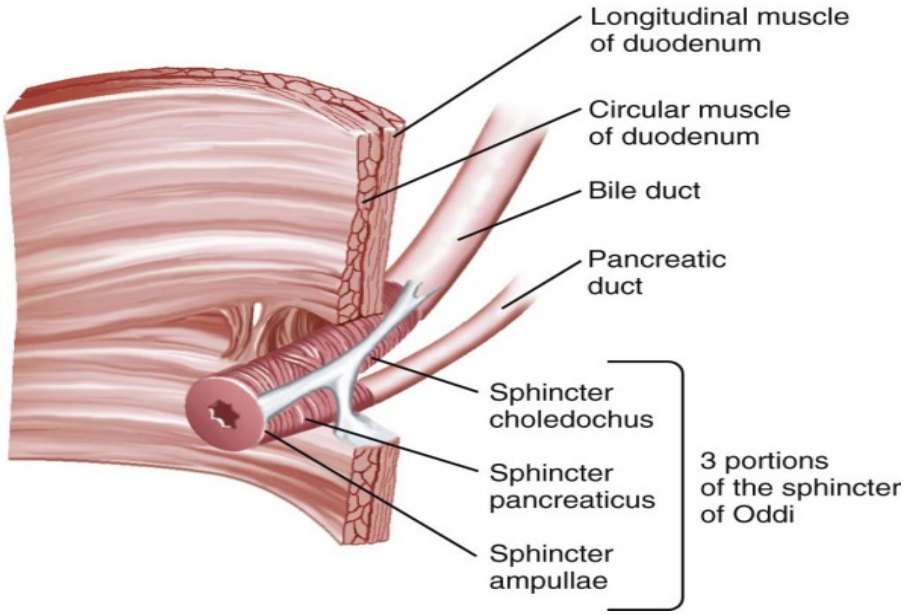


Fig.3

PANCREATIC DUCT SYSTEM

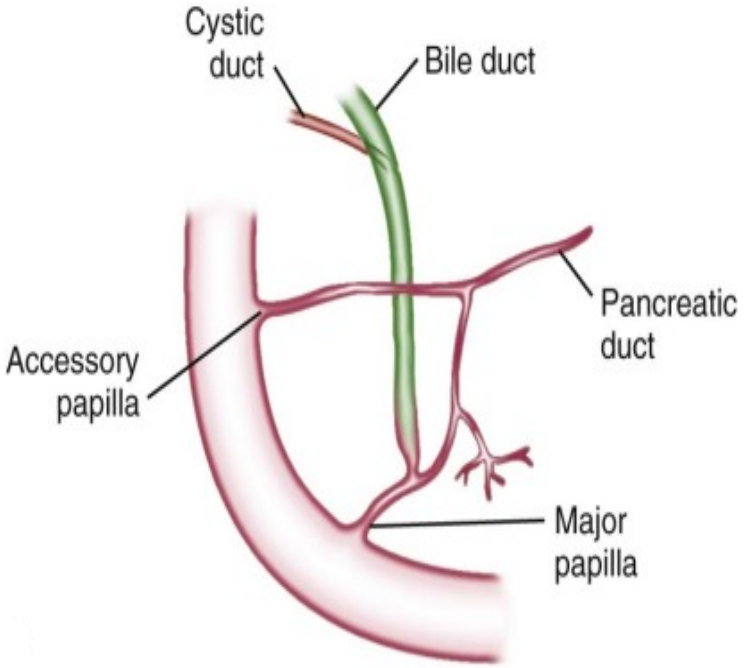


Fig.4

During fasting between periods of digestion, cycles of motor activity migrate from the stomach to the distal ileum called migrating motor complex (MMC). It starts with phase of quiescence (I), continues with phase of irregular electrical and mechanical activity (II) and ends with phase of burst of regular activity (III). They may clear the stomach and small intestine of its residual luminal contents. Inhibition of which is important during the period of endoscopic retrograde cholangiopancreatography (ERCP).

PHYSIOLOGY OF FATTY MEAL ON BILIARY TRACT AND SMALL INTESTINE:

Most fat digestion begins in the duodenum. The secretion of cholecystokinin (CCK) is stimulated by contact of fatty acids, amino acids and peptides. It is secreted in the duodenum and proximal jejunum by the endocrine 'I' cells. It is also found in nerves in the distal ileum and colon. Cholecystokinin produced contraction of the gallbladder and increases the secretion of pancreatic juice rich in enzymes.

Secretin is secreted by S cells of the duodenum and proximal jejunum. Secretin increases bicarbonate secretion by the duct cells of the biliary tract and pancreas, resulting in the secretion of a watery and alkaline pancreatic juice. It induces digestive enzyme rich pancreatic secretion by augmenting the action of CCK. It cause contraction of the pyloric sphincter and decreases the secretion of gastric acid.

Neurotensin, a polypeptide hormone is produced by neurons and cells in the mucosa of the ileum on stimulation by the fatty acids. It inhibits gastrointestinal motility and increases ileal blood flow.

PHARMACOKINETICS:

HYOSCINE-N-BUTYL BROMIDE-

Hyoscine-N-butyl bromide is a choliniceptor antagonist, acting on the muscarinic receptors M_2, M_3 of smooth muscle cells of the intestine. It functions as a parasympatholytic by blocking the effects of parasympathetic autonomic discharge. It is widely distributed in the body and achieves higher levels in central nervous system within 30 minutes to one hour, exhibiting its anti-muscarinic effects. It has a half-life of 2 hours. It is excreted unchanged in urine to the extent of 60%. It acts by binding to the muscarinic receptors and inhibiting the adenylyl cyclase and preventing inositol triphosphate (IP_3) release. Gastrointestinal smooth muscle motility from stomach to colon is diminished. It relaxes the visceral walls. Therefore gastric emptying time is prolonged and intestinal transit time is lengthened. A complete muscarinic blockade still cannot totally abolish the motility of the gastrointestinal system, as it is also under the control of local hormones and non-cholinergic neurons of the enteric nervous system. The basal gastric acid secretion is reduced. It causes drowsiness, amnesia, pupillary dilatation, cycloplegia, dryness of lacrimal and sweat secretion, initial bradycardia by blocking muscarinic receptors of the vagal postganglionic fibers in sinoatrial node, vagal slowing and a relative tachycardia, urinary retention in benign prostatic hypertrophy.

DROTAVERINE-

Drotaverine is an anti-spasmodic agent, related to papaverine. It is a phosphodiesterase-IV inhibitor and has no anticholinergic effects. It decreases the influx of calcium into smooth muscles by inhibiting

phosphodiesterase and intracellular cAMP levels. It decreases the tone of smooth muscles in visceral organs and decreases intestinal peristalsis. It does not cross the blood brain barrier. It has a half-life of 12 minutes. It is excreted minimally in urine. It occasionally causes arrhythmia, arterial hypotension, palpitations, constipation, sweating, flushing. It is contraindicated in II-III degree atrioventricular block and cardiogenic shock.

TECHNIQUES TO FACILITATE CANNULATION:

WIRE-GUIDED AND CONTRAST GUIDED CANNULATION (Fig.5)-

A dual lumen catheter is preloaded with a guide wire which is hydrophilic tipped. The ERCP cannula size varies from 5F to 7F with a tapered tip accepting a guide wire of 0.035-inch[7]. Catheter tip is advanced after engaging it into the papilla at 11'o clock position in the bile duct direction. The guide wire is advanced by manipulation, into the bile duct. Once it has advanced several centimeters, its location is verified under fluoroscopy[19]. If the pancreatic duct is cannulated instead of the bile duct, the guidewire is withdrawn. The guide wire is advanced after repositioning the sphincterotome, under fluoroscopy. To delineate the anatomy, contrast injection is done when measures at guide wire cannulation fails[19]. Cannulation with a catheter alone, with contrast injection to delineate the biliary anatomy is another approach for selective biliary cannulation. The catheter or sphincterotome is advanced into the deeper duct, if the desired duct is injected. A success rate of 60%-70% has been reported with cannulation using cannula and contrast[20,21]. The cannulation success rates can be increased up to 97% by using a papillotome for contrast injection[20-22]. Because of increased propensity of post-ERCP acute pancreatitis, it is better to avoid repeated contrast injection into the pancreatic ducts[23,24]. Compared to contrast injection, the guide wire technique lowers the chances of post-ERCP pancreatitis (PEP), by reducing the need for precut sphincterotomy and avoids unintentional pancreatic duct contrast injection[19,25,26]. To achieve a successful biliary cannulation, fewer cannulation attempts of the papilla is much more important than whether contrast or guide wire is used first[27]. Compared to a standard ERCP catheter, a hydrophilic guide wire achieves selective CBD cannulation at a higher rate[28]. It is preferable to use wire guided cannulation technique.

PRECUT TECHNIQUES (Fig.6)-

With failure of standard methods in cannulation, a precut papillotomy with a "precut" papillotome or a needle knife is used[29,30]. In the anterior wall of the major papilla, an incision is made with electrocautery needle knife. Depending on the location and extent of the incision on the papilla, this technique is named as needle knife fistulotomy, needle knife papillotomy or needle knife sphincterotomy[24,31-33]. Repeated strokes must be longitudinal and shallow enough with needle knife to prevent perforation and dynamic enough to prevent needle adhering to the tissue being cut[24]. The incision should be longitudinal to the intraduodenal portion of the papilla of length of 5-8mm. This technique, without increasing the rate of complications leads to increase in the success rates of selective biliary cannulation[24,34]. The risk of perforation of the duodenum, acute pancreatitis and bleeding is high if performed without expertise[35]. Pancreatic stent placement prior to precut sphincterotomy helps to delineate the anatomy and prevents injury to the pancreatic sphincter during precut of the common bile duct (Fig.7). PEP was seen in 5.3% of patients in the persistent cannulation attempts group and 2.5% of patients in the early precut group. Bleeding, perforation, cholangitis and pancreatitis rates were 6.3% in the persistent cannulation attempts group and 5.0% in the early precut group. PEP risk is reduced with early precut without a reduction in overall complication rates[36]. PEP was independently associated with the increased number of

WIRE-GUIDED CANNULATION

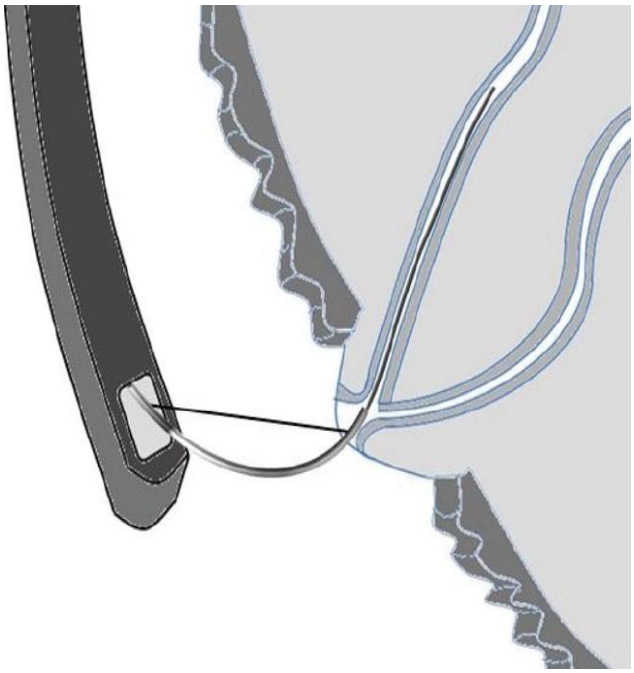


FIG.5

PRE-CUT TECHNIQUE

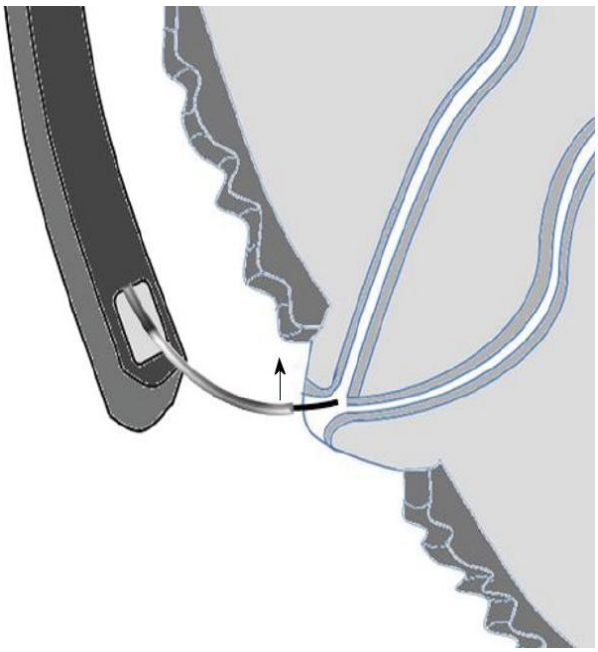


FIG.6

PRECUT PAPILLOTOMY USING NEEDLE KNIFE OVER PANCREATIC STENT

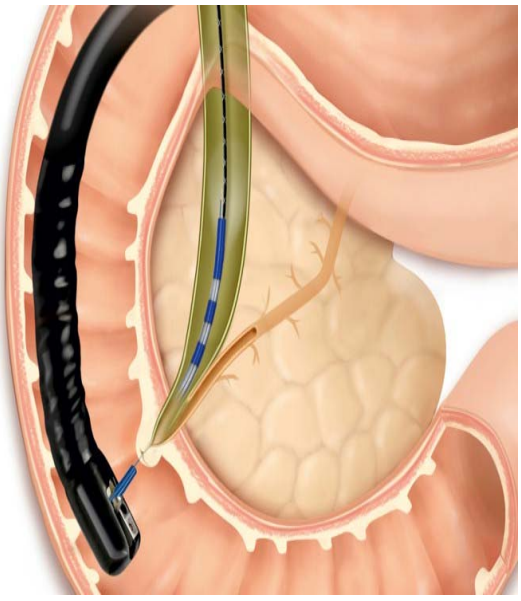


Fig.7

SUPRAPAPILLARY PUNCTURE OF THE COMMON BILE DUCT - FISTULOTOMY

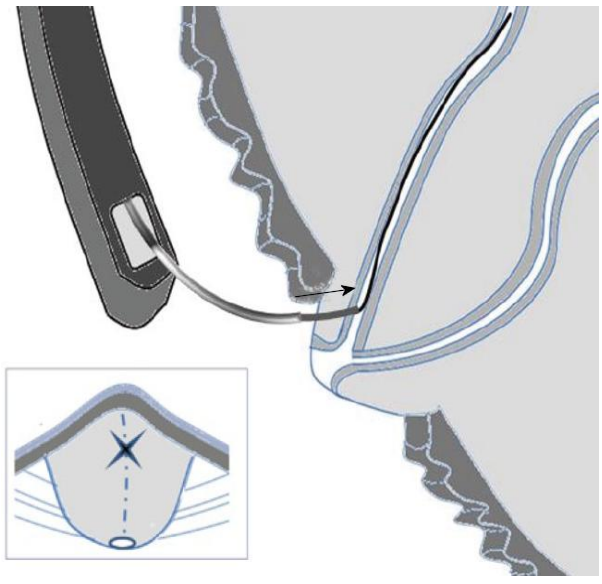


Fig.8

cannulation attempts of papilla. Needle knife sphincterotomy was not an independent predictor of PEP[37,38]. Conventional sphincterotomy is done after a precut sphincterotomy[39].

Suprapapillary puncture of the CBD, needle knife fistulotomy was first described as early as 1978 for diagnostic and therapeutic procedures (Fig.8)[40,41]. A polyethylene Artifon catheter, with a flexible metallic sheath at the distal end and a 18-gauge needle, allows puncture of the bile duct and guide wire insertion at the proximal third of the line between the papillary ostium and transversal fold, in the direction of the CBD. Contrast is then injected to obtain a cholangiogram. Successful cannulation rate of 90% with needle knife fistulotomy after unsuccessful standard guide wire cannulation has been reported[42].Complications like perforation, minor bleed and submucosal injection has also been reported[41]. Significant differences in perforation or pancreatitis rates were not observed. With adequate expertise this technique is promising.

PANCREATIC TECHNIQUES-

Pancreatic technique improves biliary cannulation when pancreatic duct is preferentially cannulated unintentionally. Guide wire placement into pancreatic duct (P-GW) through a cannula (Fig.9) improves the selective biliary cannulation rate by stabilizing the ampulla of Vater and this also straightens the distal common bile duct[43-46]. The guide wire is left in the pancreatic duct and fluoroscopically monitored and the cannula is removed[45]. Cannulation of the bile duct is attempted by reinserting the cannula next to the guide wire[47]. Prophylaxis of post-ERCP pancreatitis can be done by placing a small caliber pancreatic stent 3F or 4F, over the pancreatic duct guide wire. In difficult cannulation, with P-GW technique, 73% success of selective bile duct cannulation is reported. With prophylactic pancreatic stenting, post-ERCP pancreatitis (PEP) was lower[46]. In difficult cannulation, pancreatic guide wire technique is a safe and effective method to be adopted.

Pancreatic precut sphincterotomy (PPS) is another technique for selective biliary cannulation (Fig.10). It is done by cannulating the main pancreatic duct deeply, then orienting the sphincterotome at 11 o'clock position in the direction of the bile duct and performing the pancreatic sphincterotomy to expose the bile duct orifice or the bile duct itself[48]. Success rate of 85% has been reported in patients who failed standard cannulation, with or without pancreatic duct stent placement. Complications like post-sphincterotomy bleeding, pancreatitis, retroperitoneal perforations have been reported and managed conservatively[48]. Significant difference in the success and complication rates between PPS and needle knife sphincterotomy has not been observed[49].

Pancreatic stenting to divert a catheter or guide wire into the bile duct to facilitate biliary cannulation can be done (Fig.11). If this technique fails, the pancreatic stent acts as a guide to perform a precut sphincterotomy or transpancreatic sphincterotomy (Fig.12) with a standard sphincterotome inserted towards the biliary orifice into the pancreatic duct above the pancreatic stent[49]. 97.4% success rates have been reported when pancreatic duct stenting were used in difficult cannulations. Pancreatic duct stent placement straightens the distorted ampullary anatomy caused by periampullary diverticula, which makes conventional biliary cannulation difficult[50].

PHARMACOLOGIC METHODS TO EASE CANNULATION-

PANCREATIC GUIDE WIRE TECHNIQUE

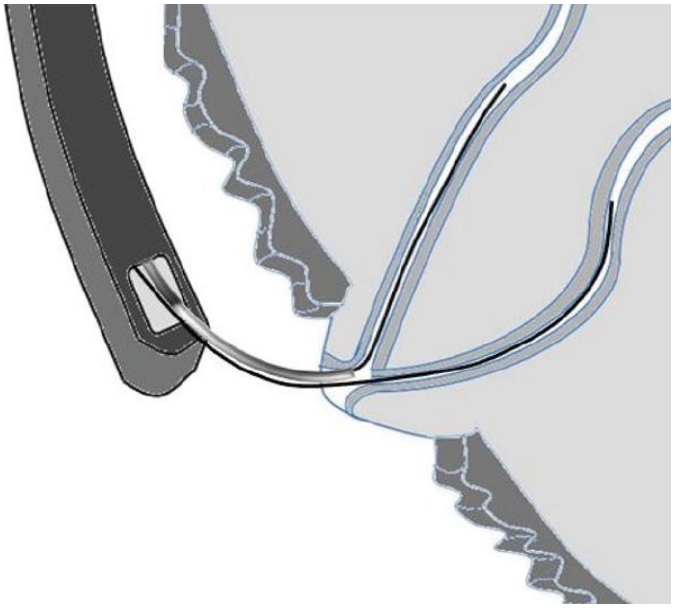


Fig.9

TRANSPAPILLARY PANCREATIC SPHINCTEROTOMY

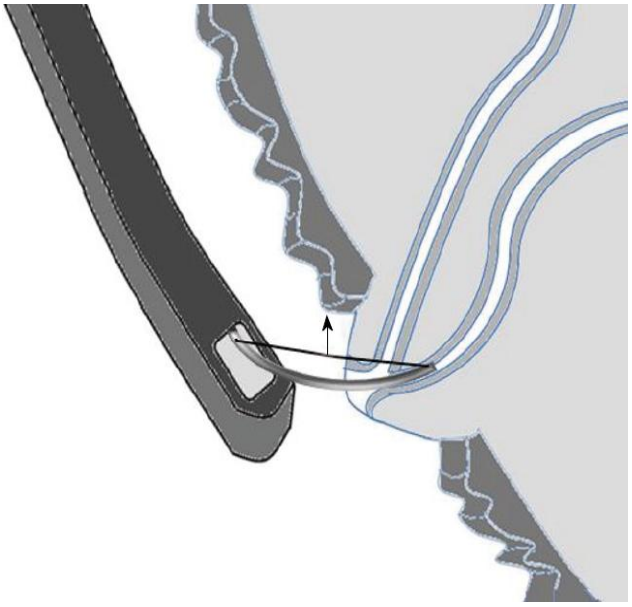


Fig.10

PANCREATIC STENTING AND CANNULATION

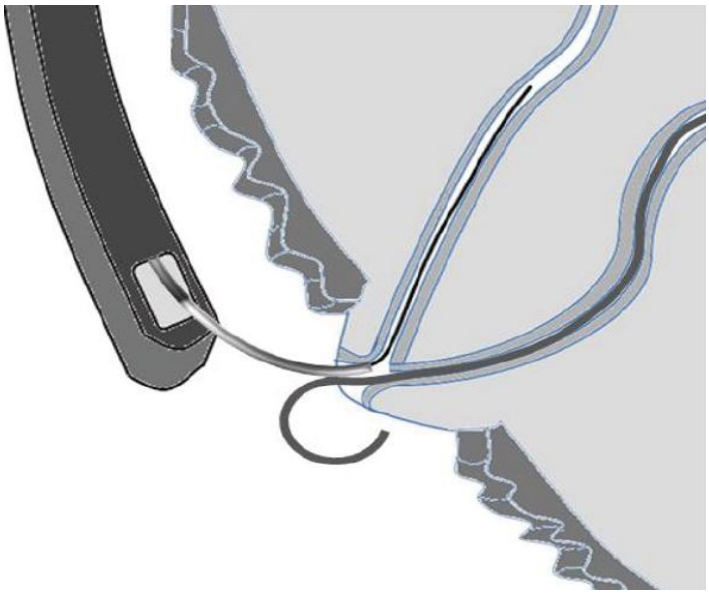


Fig.11

TRANSPANCREATIC SPHINCTEROTOMY OVER PANCREATIC STENT

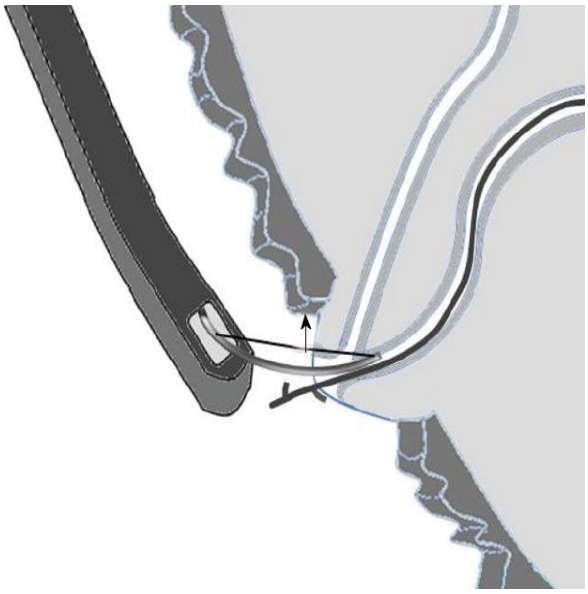


Fig.12

Interventions with the help of pharmacologic agents have been used to facilitate cannulation, apart from the technical methods to increase successful cannulation rates. The data is high for secretins role in cannulation of minor papilla. Secretin is a polypeptide secreted by the S cells of the mucosa of proximal small intestine in response to acid in the lumen. Secretin acts on the G-protein-coupled receptors, stimulating the secretion of water and bicarbonate from pancreatic duct cells[51]. In pancreas divisum, the predominant dorsal pancreatic duct drainage is facilitated by increasing the production of pancreatic secretions which can be confirmed by identifying the minor papilla, cannulating and injecting contrast into it. Success rate of 89% have been reported with the use of secretin in failed conventional minor papilla cannulation[51].

Methylene blue has also been used to identify minor papilla to facilitate cannulation, by spraying it in the region of the minor papilla or by injecting methylene blue mixed contrast medium through the major papilla into the ventral pancreatic duct, in incomplete pancreas divisum[52].

Intraduodenal acid infusion (IDAI) induces secretin release physiologically. It is a cost-effective method to enhance minor papilla cannulation rates to 80%[53,54].

Cholecystokinin (CCK) hormone stimulates gallbladder contraction. It relaxes the sphincter of Oddi and may ease ampullary cannulation. A CCK agonist Sincalide (Kinevac), a synthetic carboxyl-terminal octapeptide has been used to facilitate cannulation[55]. It can aid in cannulation with standard catheter technique without guide wire mediated cannulation or needle knife papillotomy. The comparative results are ambiguous[56].

Topical nitroglycerin is proposed to relax the sphincter of Oddi but there was no difference in selective bile duct cannulation rates[57,58].

LIQUID FATTY MEAL-

Fat is a stimulator of bile secretion and causes the sphincter of Oddi to relax. Orally given liquid fatty meal, 1 hour before the procedure made the CBD/pancreatic duct opening easily identifiable without any difference in the success rates of cannulation[59]. The cannulation and fluoroscopy times were shorter with fatty meal. Fatty meal is a simple method which is less expensive for facilitating cannulation and decreasing the duration of fluoroscopy at ERCP.

MATERIALS AND METHODS

MATERIALS AND METHODS

During the period from June 2013 to March 2014, 60 patients admitted for endoscopic retrograde cholangiopancreatography (ERCP) with normal appearing ampulla on endoscopy at Madras Medical College and Hospital, Chennai, fulfilling the inclusion criteria were taken-up for the study.

In the present study, Ultrasonography (USG), Contrast enhanced Computed tomography (CECT), Magnetic Resonance Cholangiopancreatography (MRCP) were done prior to the procedure.

After careful history taking regarding allergy to milk, features of obstructive uropathy in males, pregnancy and breast feeding in females, physical signs were recorded in detail. Investigations like serum creatinine, intra-ocular pressure for glaucoma, electrocardiography, echocardiography and upper gastrointestinal endoscopy for anatomic alterations were done. Corresponding clinical diagnosis were recorded.

Baseline duodenal motility rates were recorded during upper gastrointestinal endoscopy, by positioning the scope in II part of duodenum with air inflation.

All patients planned for ERCP were subjected to protocol screening as per the proforma and vitals like baseline pulse rate and blood pressure were documented. These patients were subjected to upper gastrointestinal endoscopy after a fasting period of atleast eight hours, for documentation of number of duodenal contractions per minute. Patients were subjected randomly into the three groups. Fatty meal, 200ml of skimmed milk (1.7% fat) was given orally, one hour prior to the procedure, to allow for gastric emptying. Hyoscine-N-butyl bromide 20mg/ Drotaverine hydrochloride 40mg was given intravenously, fifteen minutes before procedure. The ERCP procedure was done under IV sedation of pentazocine 30mg with promethazine 50mg given slowly. Side viewing scope was intubated orally and positioned in the second part of duodenum and shortening of the scope done and ampulla was identified. Using biliary cannula or pancreatic cannula, cannulation of the ampulla was done with or without the 0.035" GW assistance technique to confirm the position of the cannula to be in the bile duct(running along the right para-vertebral region) or the pancreatic duct(running across the L2 vertebrae). The bile duct is cannulated by directing the cannula in the 11'o clock position and pancreatic duct is cannulated by directing the cannula in the 2'o clock position. Hemodynamic parameters were recorded during the procedure along with the duodenal contraction rates. Success of cannulation with or without the use of needle knife sphincterotome, time taken to achieve successful cannulation into the desired ducts, complications after ERCP and any adverse effects of drugs were noted. Any additional dosage or supplemental drugs to achieve duodenal hypomotility were recorded. Then the appropriate procedure is completed depending upon the pathology identified.

STUDY PERIOD: From June 2013 to March 2014

Inclusion Criteria:

- All patients aged >18 years, undergoing ERCP at Madras Medical College.
- Patients with normal appearing ampulla subjected to ERCP for the first time.

Exclusion Criteria:

- Patients with a known allergy to milk
- Glaucoma
- Patient with Billroth II gastrectomy
- Obstructive uropathy
- Hypotension (systolic blood pressure < 100 mmHg)
- Impaired renal function (serum creatinine> 133μmol/L)
- Second-degree and third-degree atrioventricular block
- Pregnant or breastfeeding women
- Heart failure

INTERVENTION:

- Approximately one hour before ERCP procedure, patients were given fatty meal (Fat-1.7%) 200ml of milk.
- 15 minutes before ERCP, Drotaverine hydrochloride 40mg/ Hyoscine-N-butyl bromide 20mg was given intravenously.

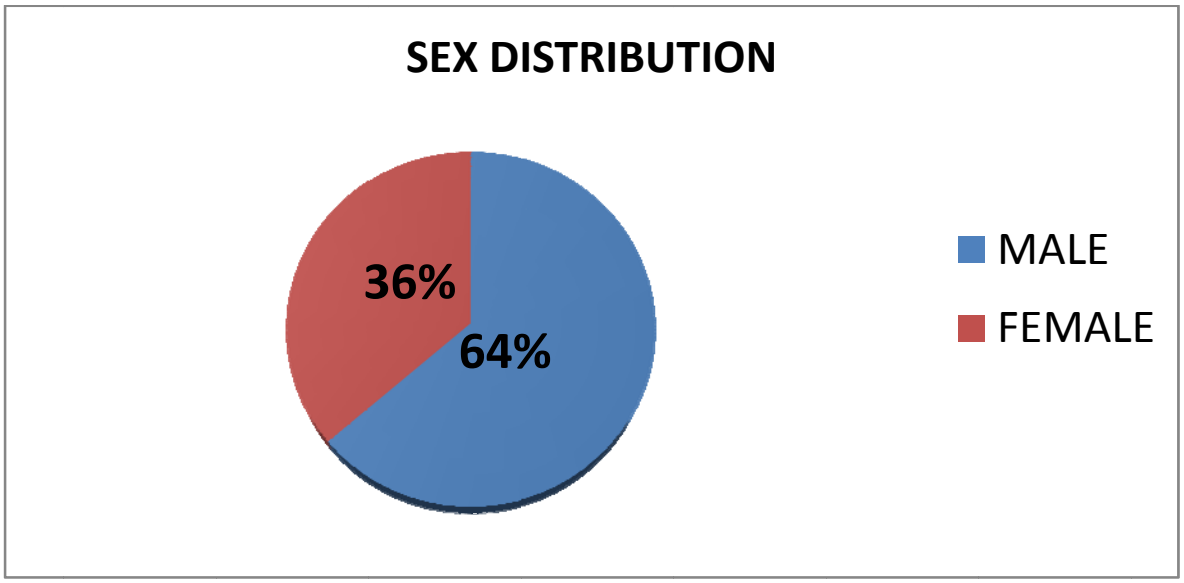
OBSERVATION

OBSERVATION

A) HYOSCINE-N- BUTYL BROMIDE GROUP:

Sex Distribution:

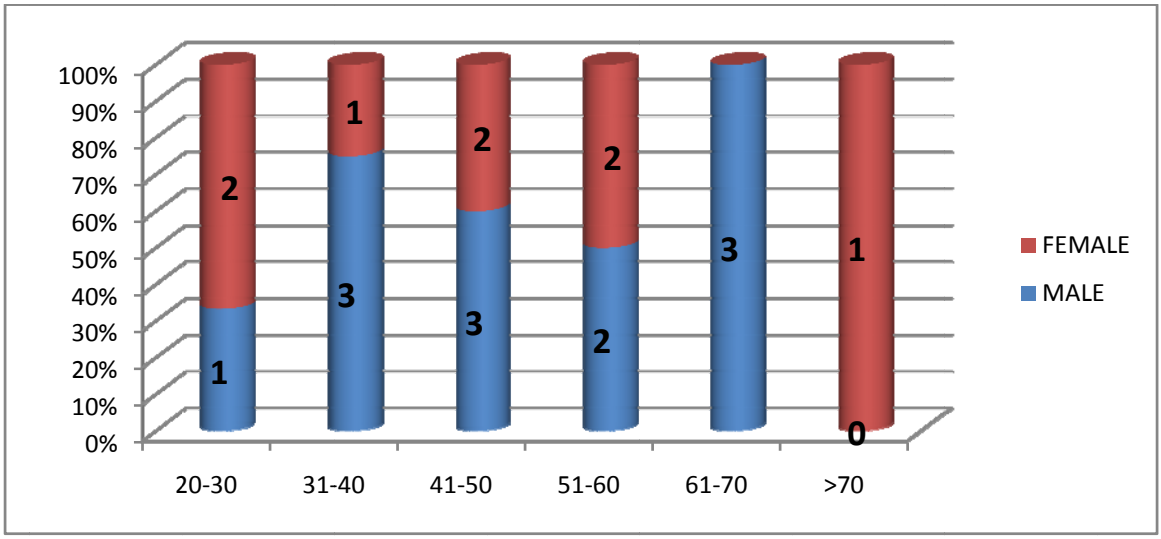
MALE	FEMALE
14	08



Age distribution:

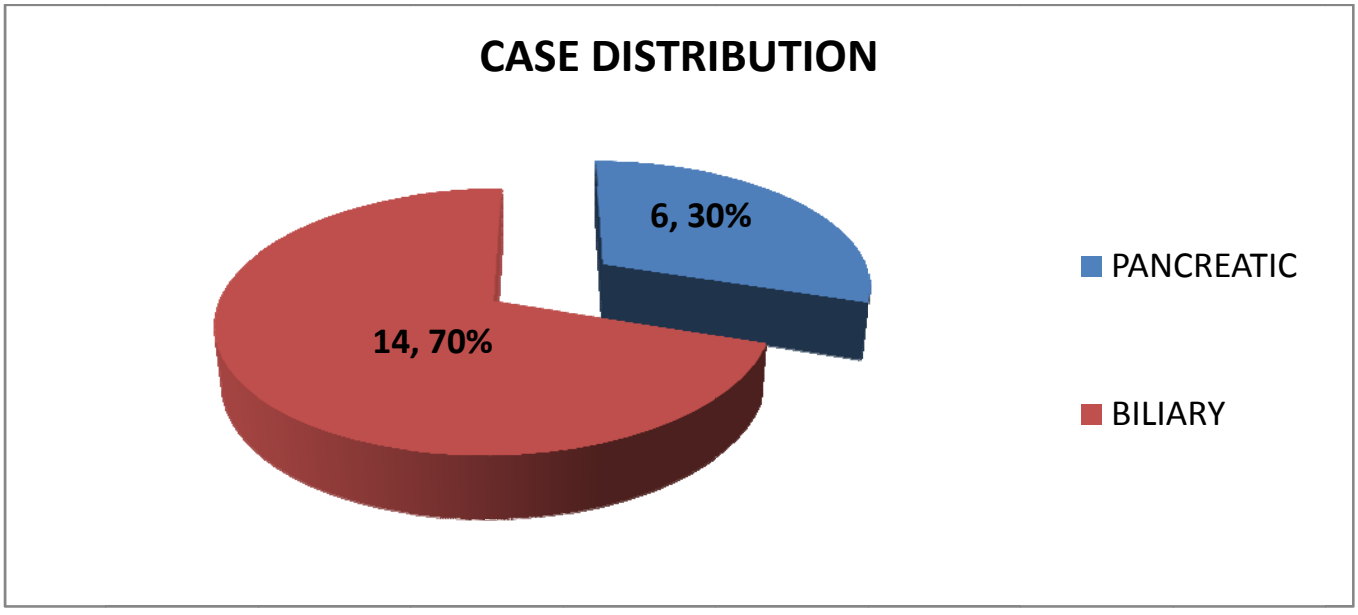
AGE	MALE	FEMALE	TOTAL
20-30	1	2	3
31-40	3	1	4
41-50	3	2	5
51-60	2	2	4
61-70	3	0	3
>70	0	1	1
TOTAL	12	08	20

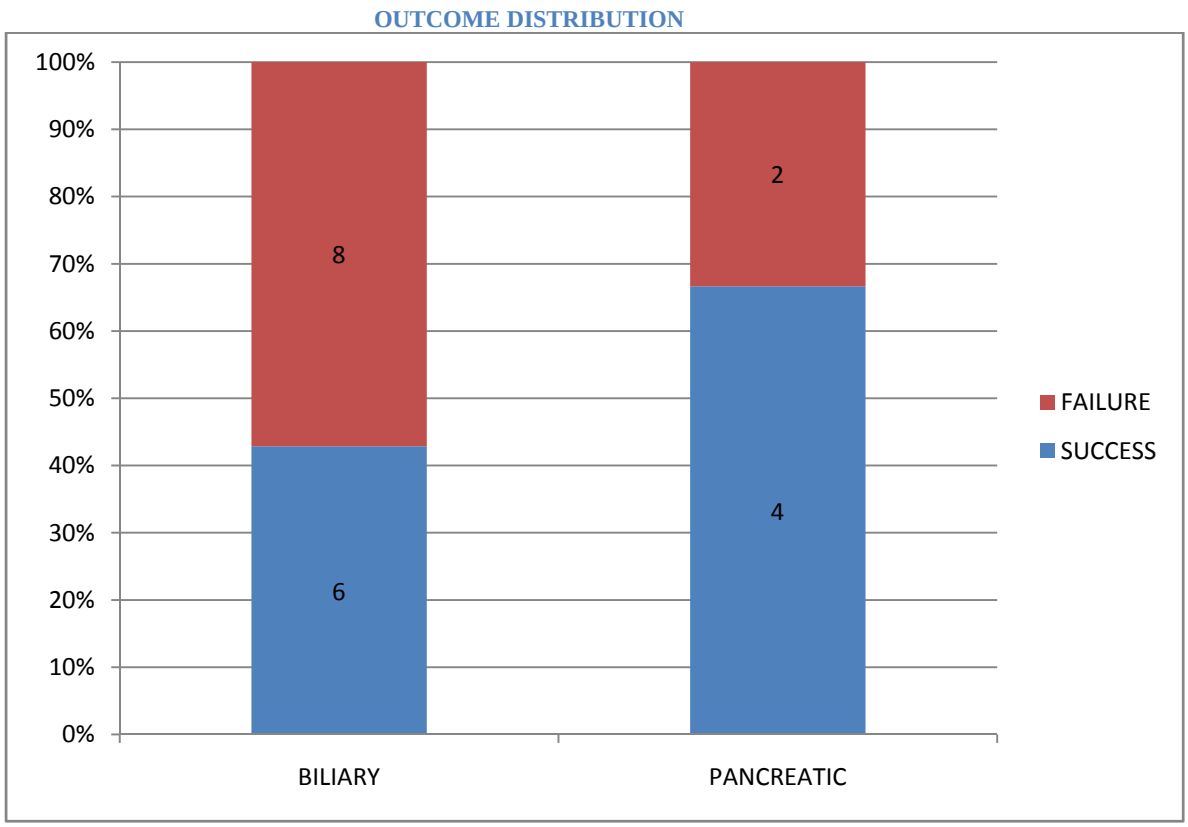
AGE WISE DISTRIBUTION



DIAGNOSIS:

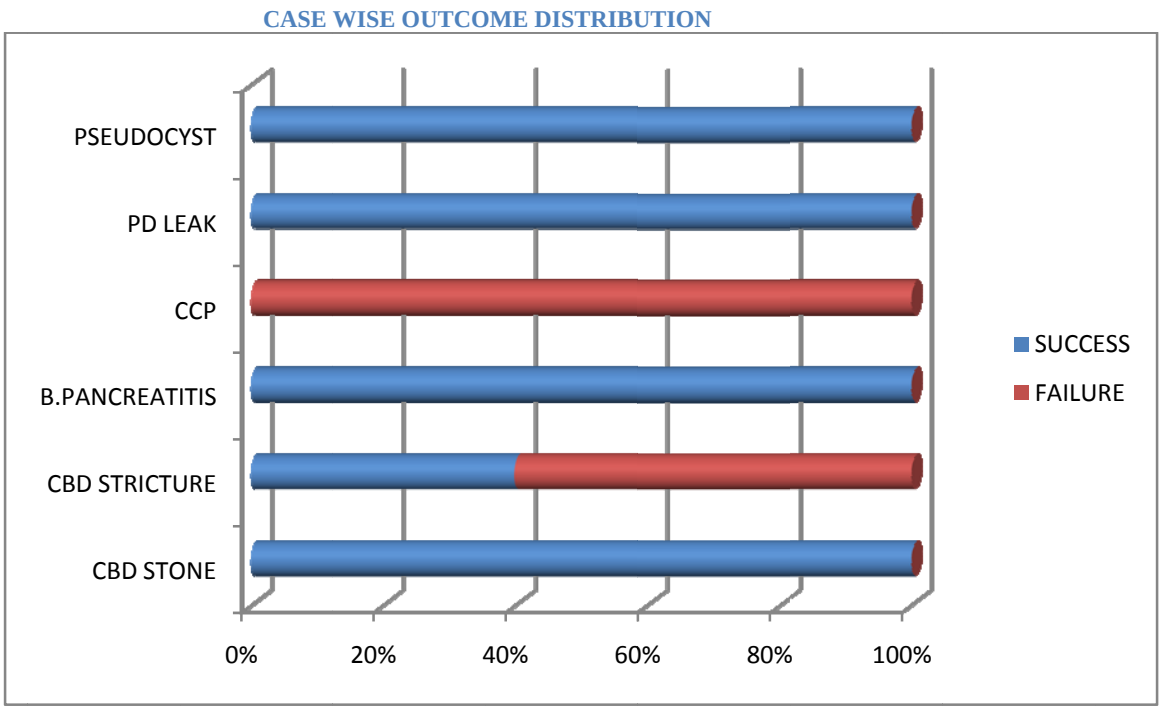
CASES	MALE	FEMALE	TOTAL	SUCCESS		FAILURE	
				MALE	FEMALE	MALE	FEMALE
PANCREATIC	2	4	6	2	2	0	2
BILIARY	10	4	14	4	2	6	2
TOTAL	12	08	20	06	04	06	04





CASE DISTRIBUTION:

CASES	MALE	FEMALE	TOTAL	SUCCESS		FAILURE	
				MALE	FEMALE	MALE	FEMALE
CBD STONE	0	2	2	0	2	0	0
CBD STRICTURE	4	1	5	2	0	2	1
B.PANCREATITIS	0	2	2	0	2	0	0
CCP	0	1	1	0	0	0	1
PD LEAK	0	1	1	0	1	0	0
PSEUDOCYST	2	0	2	2	0	0	0



DUODENAL MOTILITY (DM/minute):

FOR ALL (Male and Female):

FACTORS	DM-BASELINE	DM-PROCEDURE	DM-Diff
Mean	14.1	0.4	13.7
Median	13.5	0	13.5
Mode	12	0	16
Std Dev	2.118962	0.860232527	2.260531

Males:

FACTORS	DM-BASELINE	DM-PROCEDURE	DM-Diff
Mean	13.333333	0.5	12.83333
Median	12.5	0	12
Mode	12	0	12
Std Dev	1.9720266	0.957427108	2.266912

Females:

FACTORS	DM-BASELINE	DM-PROCEDURE	DM-Diff
Mean	15.25	0.25	15
Median	16	0	16
Mode	16	0	16
Std Dev	1.7853571	0.661437828	1.5

Heart disease patients:

The mean difference in duodenal motility for 5 heart disease patients was 12.2/minute.

CANNULATION TIME (in minutes):

FACTORS	All	MALE	FEMALE
Mean	4	4.5	3.25
Median	3.5	4.5	3.5
Mode	3	6	4
Std Dev	1.673320053	1.892969449	0.829156198

Heart disease patients:

The mean cannulation time for 5 heart disease patients was 4 minutes.

SUCCESS RATE:

Successful cannulation was achieved in 10 of 20 patients. The success rate is 50%

PULSE RATE (per minute):

FACTORS	All	MALE	FEMALE
Mean	51.55	49.33333333	54.875
Median	48	46	52

Mode	52	42	52
Std Dev	12.54780857	11.84154645	12.83975759

The pulse rate at baseline and maximal pulse rate attained during the procedure was documented and analyzed.

Heart disease patients:

The mean difference in pulse rate for 5 heart disease patients was 63.8/minute.

BLOOD PRESSURE (in mm of Hg):

The blood pressure at baseline and maximal pressure attained during the procedure was documented and analyzed.

FOR ALL (Male and Female):

FACTORS	Diff (Sys)	Diff (Dia)
Mean	18.3	15.7
Median	20	13
Mode	20	10
Std Dev	7.51731335	8.860586888

FOR MALE:

FACTORS	Diff (Sys)	Diff (Dia)
Mean	19.5	16.66666667
Median	20	19
Mode	20	22
Std Dev	7.70822072	9.357112565

FOR FEMALE:

FACTORS	Diff (Sys)	Diff (Dia)
Mean	16.5	14.25

Median	16	10
Mode	12	10
Std Dev	6.837397166	7.838207703

Heart disease patients:

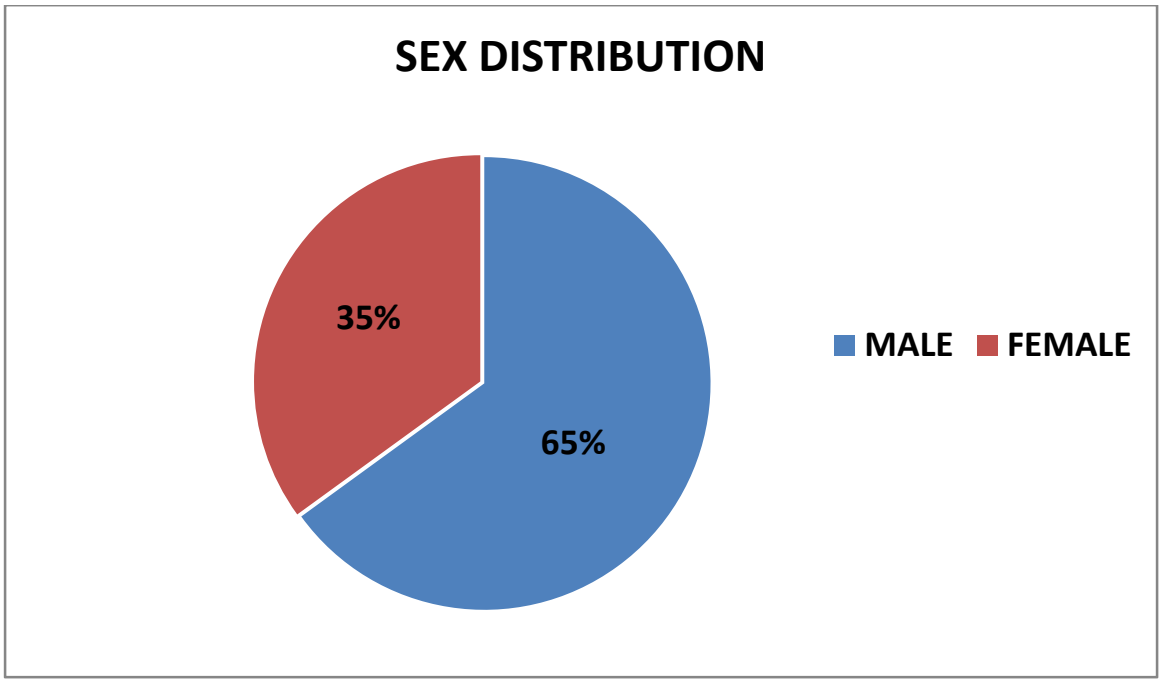
The mean difference in systolic blood pressure for 5 heart disease patients was 18 mm of Hg.

The mean difference of diastolic blood pressure for 5 heart disease patients was 11.2 mm of Hg.

B) DROTAVERINE GROUP:

Sex Distribution:

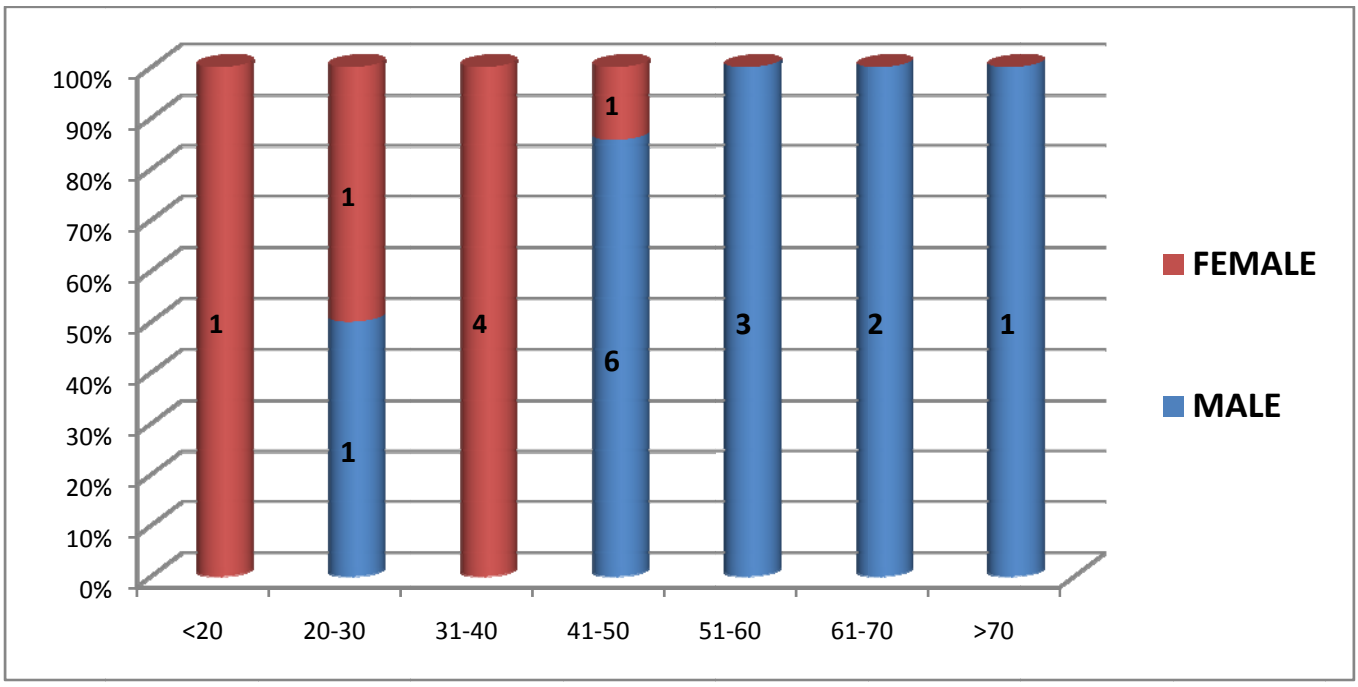
MALE	FEMALE
13	07



Age distribution:

AGE	MALE	FEMALE	TOTAL
<20	0	1	1
20-30	1	1	2
31-40	0	4	4
41-50	6	1	7
51-60	3	0	3
61-70	2	0	2
>70	1	0	1
TOTAL	13	07	20

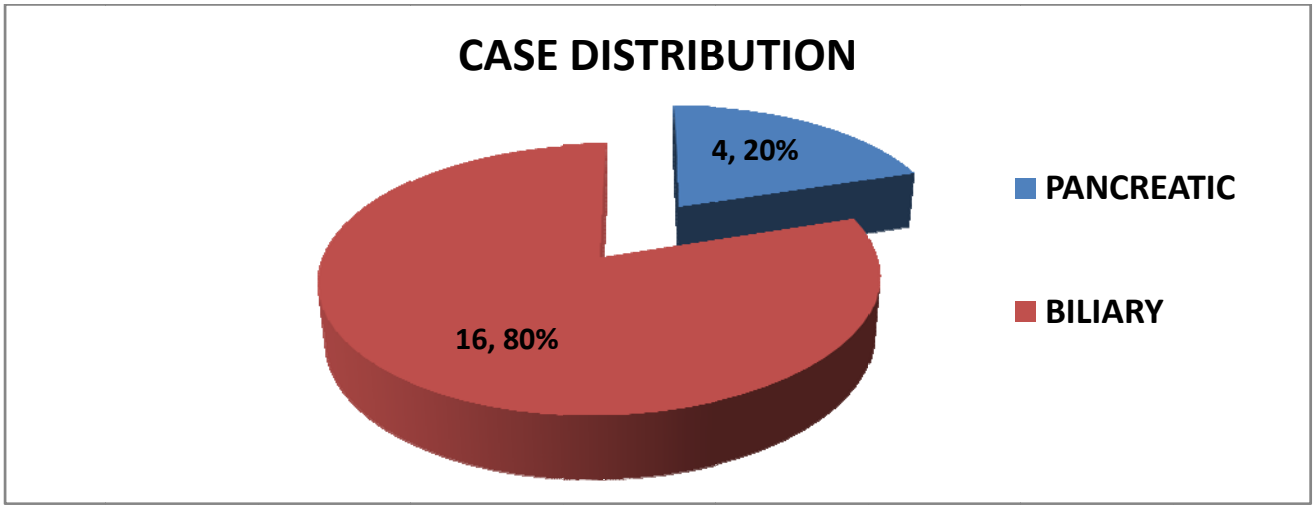
AGE WISE DISTRIBUTION

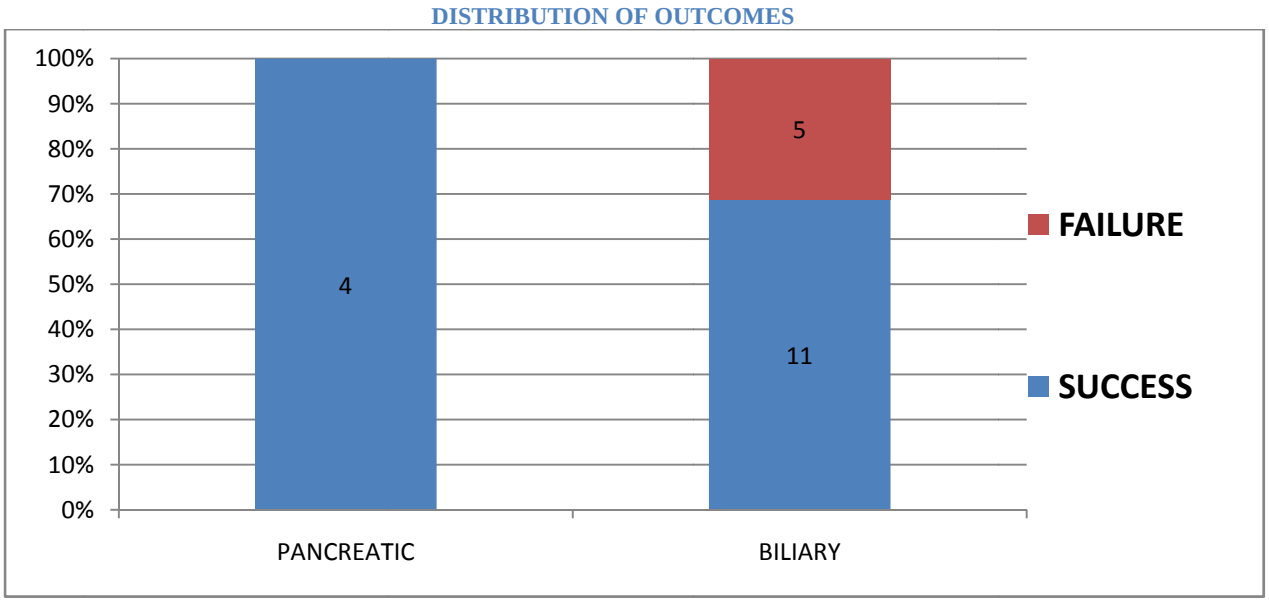


DIAGNOSIS:

CASES	MALE	FEMALE	TOTAL	SUCCESS		FAILURE	
				MALE	FEMALE	MALE	FEMALE

PANCREATIC	3	1	4	3	1	0	0
BILIARY	10	6	16	8	3	2	3
TOTAL	13	07	20	11	04	02	03

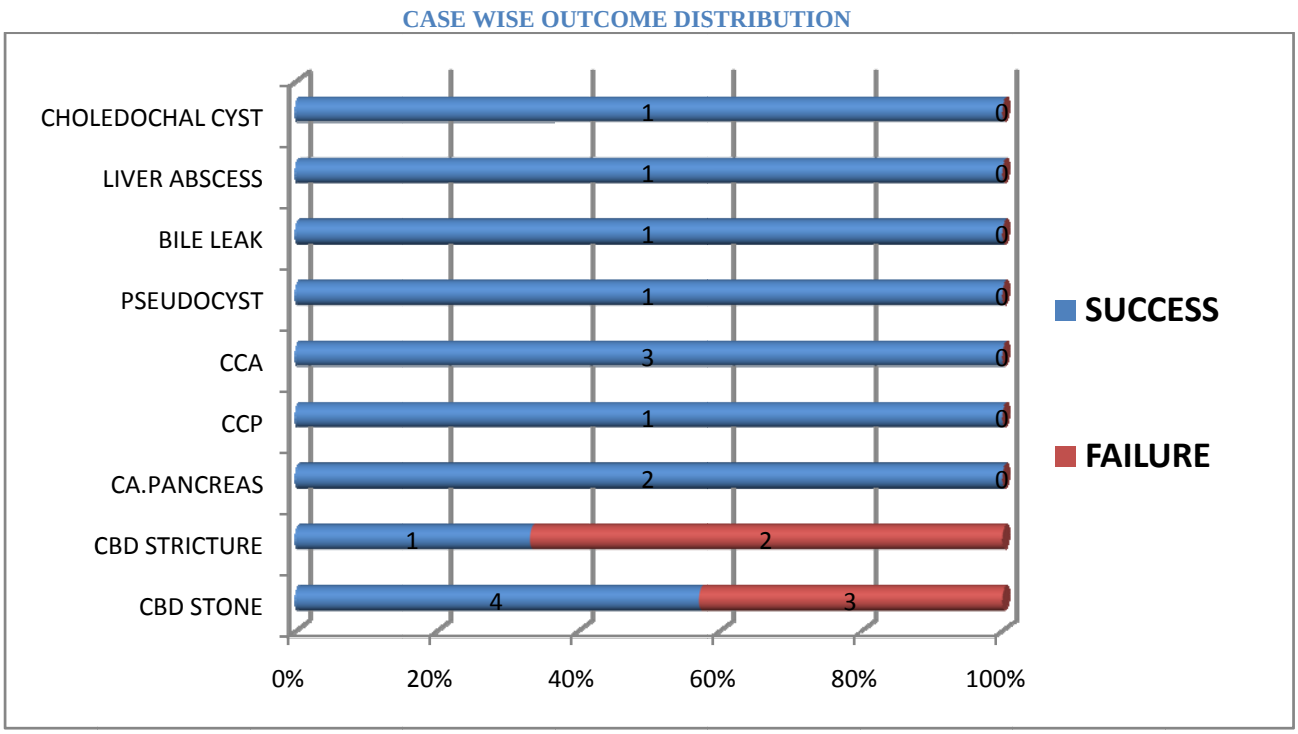




CASE DISTRIBUTION:

CASES	MALE	FEMALE	TOTAL	SUCCESS		FAILURE	
				MALE	FEMALE	MALE	FEMALE

CBD STONE	3	4	7	3	1	0	3
CBD STRICTURE	3	0	3	2	0	2	0
CA. PANCREAS	1	1	2	1	1	0	0
CCP	1	0	1	1	0	0	0
HILAR CCA	3	0	3	3	0	0	0
PSEUDOCYST	1	0	1	1	0	0	0
BILE LEAK	0	1	1	0	1	0	0
LIVER ABSCESS	1	0	1	1	0	0	0
CHOLEDOCHAL CYST	0	1	1	0	1	0	0



DUODENAL MOTILITY (DM/ minute):

FOR ALL (Male and Female):

FACTORS	DM-BASELINE	DM-PROCEDURE	DM-Diff
Mean	13.75	0.7	13.05
Median	14	0	13

Mode	15	0	12
Std Dev	1.9968726	1.144552314	2.13248681

FOR MALE:

FACTORS	DM-BASELINE	DM-PROCEDURE	DM-Diff
Mean	13.461538	0.461538462	13
Median	14	0	13
Mode	15	0	12
Std Dev	1.9060787	0.929465075	1.83973242

FOR FEMALE:

FACTORS	DM-BASELINE	DM-PROCEDURE	DM-Diff
Mean	14.285714	1.142857143	13.1428571
Median	14	0	13
Mode	12	0	13
Std Dev	2.0503857	1.355261854	2.5872529

Heart disease patients:

The mean difference in duodenal motility for 5 heart disease patients was 12/minute.

CANNULATION TIME (in minutes):

FACTORS	All	MALE	FEMALE
Mean	4.666666667	4.545454545	5
Median	4	5	3

Mode	3	6	3
Std Dev	2.67498702	1.924182772	4.062019202

Heart disease patients:

The mean cannulation time for 5 heart disease patients was 3.33 minutes.

SUCCESS RATE:

Successful cannulation was achieved in 15 of 20 patients. The success rate is 75%.

PULSE RATE (per minute):

FACTORS	All	MALE	FEMALE
Mean	24.2	24.15384615	24.28571429
Median	23	24	22
Mode	34	16	34
Std Dev	8.219489035	7.46114194	9.4674523

Heart disease patients:

The mean difference in pulse rate for 5 heart disease patients was 20/minute.

BLOOD PRESSURE (in mm of Hg):

The blood pressure at baseline and maximal pressure attained during the procedure was documented and analyzed.

FOR ALL (Male and Female):

FACTORS	Diff (Sys)	Diff (Dia)
Mean	9	8.7
Median	8	8
Mode	6	6
Std Dev	5.567764363	5.487257967

FOR MALE:

FACTORS	Diff (Sys)	Diff (Dia)
Mean	9.384615385	9.692307692
Median	6	10

Mode	6	6
Std Dev	6.720101436	4.951839058

FOR FEMALE:

FACTORS	Diff (Sys)	Diff (Dia)
Mean	8.285714286	6.857142857
Median	8	6
Mode	8	0
Std Dev	1.979486637	5.938459912

Heart disease patients:

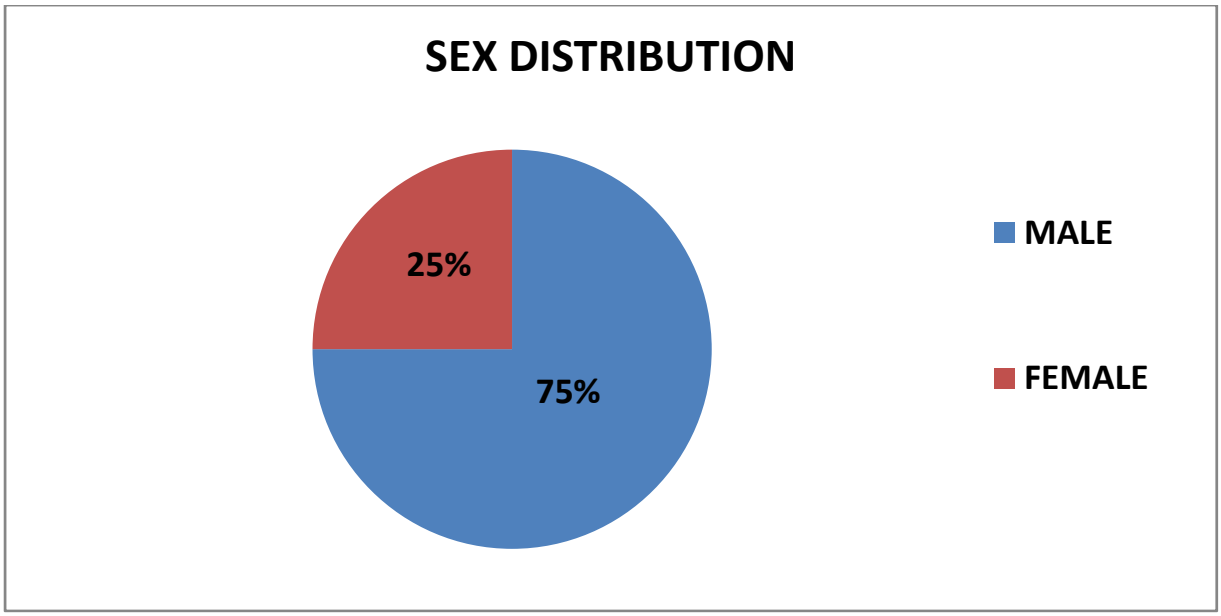
The mean difference in systolic blood pressure for 5 heart disease patients was 7.33 mm of Hg.

The mean difference of diastolic blood pressure for 5 heart disease patients was 5.66 mm of Hg.

C) FATTY MEAL GROUP:

Sex Distribution:

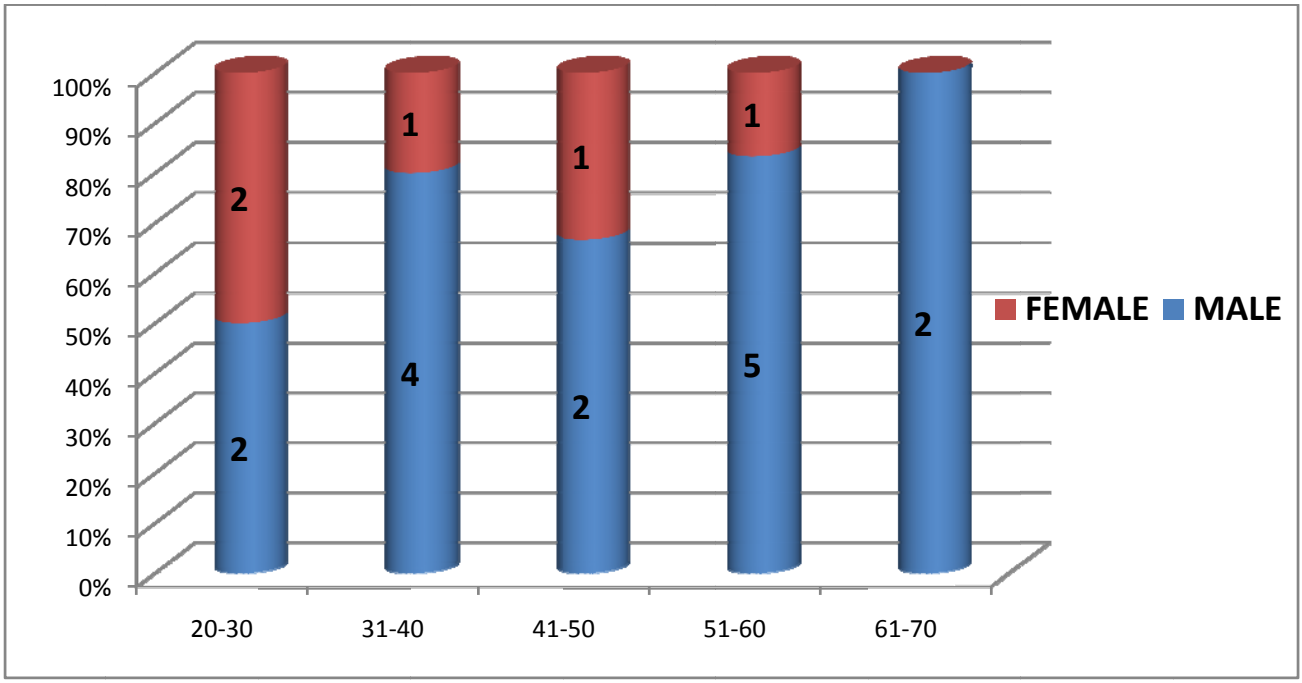
MALE	FEMALE
15	05



Age distribution:

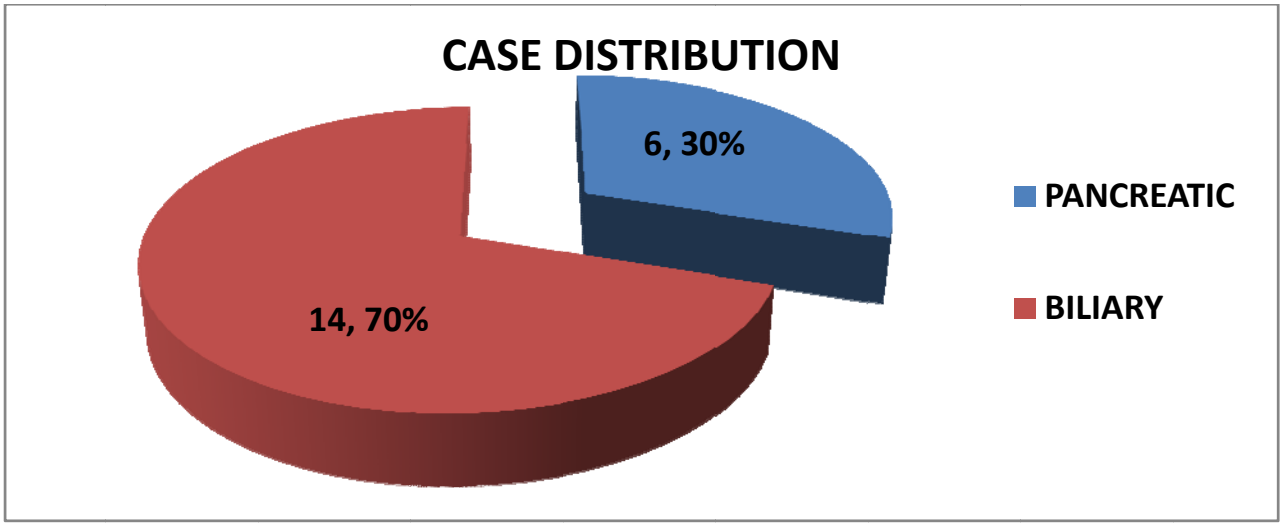
AGE	MALE	FEMALE	TOTAL
20-30	2	2	4
31-40	4	1	5
41-50	2	1	3
51-60	5	1	6
61-70	2	0	2
TOTAL	15	5	20

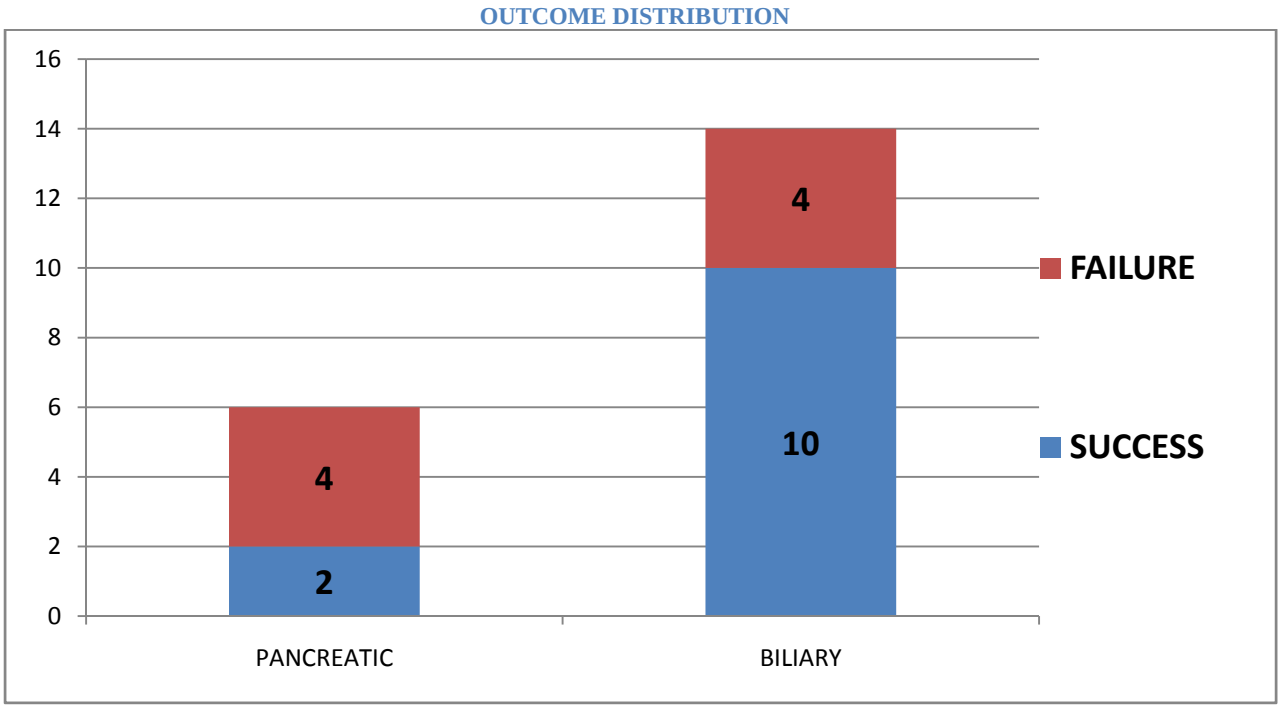
AGE WISE DISTRIBUTION



DIAGNOSIS:

CASES	MALE	FEMALE	TOTAL	SUCCESS		FAILURE	
				MALE	FEMALE	MALE	FEMALE
PANCREATIC	6	0	6	2	0	4	0
BILIARY	9	5	14	6	4	3	1
TOTAL	15	5	20	8	4	7	1

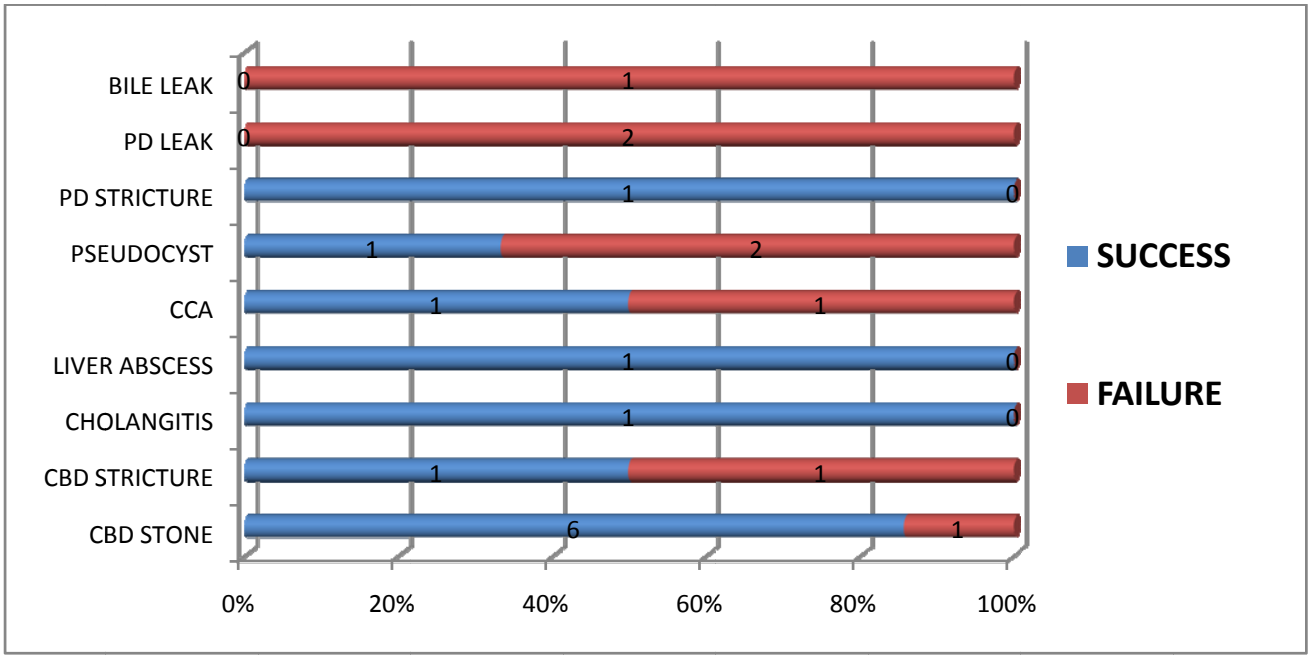




CASE DISTRIBUTION:

CASES	MALE	FEMALE	TOTAL	SUCCESS		FAILURE	
				MALE	FEMALE	MALE	FEMALE
CBD STONE	4	3	7	3	3	1	0
CBD STRICTURE	2	0	2	1	0	1	0
CHOLANGITIS	1	0	1	1	0	0	0
LIVER ABSCESS	0	1	1	0	1	0	0
CCA	2	0	2	1	0	1	0
PSEUDOCYST	3	0	3	1	0	2	0
PD STRICTURE	1	0	1	1	0	0	0
PD LEAK	2	0	2	0	0	2	0
BILE LEAK	0	1	1	0	0	0	1

CASE WISE OUTCOME DISTRIBUTION



DUODENAL MOTILITY (DM/minute):

FOR ALL (Male and Female):

FACTORS	DM-BASELINE	DM-PROCEDURE	DM-Diff
Mean	13.95	0.35	13.6
Median	14	0	13.5
Mode	14	0	13
Std Dev	1.5321553	0.90967027	1.593738

FOR MALE:

FACTORS	DM/min-BASELINE	DM/min-PROCEDURE	DM-Diff/min
Mean	14.133333	0.4	13.73333
Median	14	0	14
Mode	13	0	13
Std Dev	1.6679995	1.0198039	1.768867

FOR FEMALE:

FACTORS	DM/min-BASELINE	DM/min-PROCEDURE	DM-Diff/min
Mean	13.4	0.2	13.2
Median	14	0	13
Mode	14	0	13
Std Dev	0.8	0.4	0.748331

Heart disease patients:

The mean difference in duodenal motility for 5 heart disease patients was 13.8/minute.

CANNULATION TIME (in minutes):

FACTORS	All	MALE	FEMALE
Mean	5	4.875	5.25
Median	5	4.5	5.5
Mode	6	3	6
Std Dev	1.58113883	1.832859787	0.829156198

Heart disease patients:

The mean cannulation time for 5 heart disease patients was 5.5 minutes.

SUCCESS RATE:

Successful cannulation was achieved in 12 of 20 patients. The success rate is 60%.

PULSE RATE (per minute):

FACTORS	All	MALE	FEMALE
Mean	24.4	25.33333333	21.6
Median	25	26	18
Mode	16	16	#N/A
Std Dev	8.610458757	7.913420387	9.911609355

Heart disease patients:

The mean difference in pulse rate for all heart disease patients (5) was 27/minute.

BLOOD PRESSURE (in mm of Hg):

The blood pressure at baseline and maximal pressure attained during the procedure was documented and analyzed.

FOR ALL (Male and Female):

FACTORS	Diff (Sys) mm of Hg	Diff (Dia) mm of Hg
Mean	10.4	8.6
Median	11	8
Mode	12	8
Std Dev	4.543126677	3.231098884

FOR MALE:

FACTORS	Diff (Sys) mm of Hg	Diff (Dia) mm of Hg
Mean	10.26666667	8.666666667
Median	10	8
Mode	6	10
Std Dev	4.836895239	2.98142397

FOR FEMALE:

FACTORS	Diff (Sys) mm of Hg	Diff (Dia) mm of Hg
Mean	10.8	8.4
Median	12	6
Mode	12	6
Std Dev	3.487119155	3.878143886

Heart disease patients:

The mean difference in systolic blood pressure for 5 heart disease patients was 13.2 mm of Hg.

The mean difference of diastolic blood pressure for 5 heart disease patients was 9.2 mm of Hg.

COMPARATIVE STATISTICAL ANALYSIS OF PRIMARY AND SECONDARY OUTCOMES USING SPSS SOFTWARE:

DUODENAL ANTI-MOTILITY (Minutes):

		N	Mean	Std. Deviation	95% Confidence Interval for Mean		Min.	Max.
					Lower Bound	Upper Bound		
Difference	Hyoscine	20	13.70	2.319	12.61	14.79	10	18
	Drotaverine	20	13.05	2.188	12.03	14.07	9	18
	Milk	20	13.60	1.635	12.83	14.37	11	17

ANOVA

	Sig.
Diff	0.567

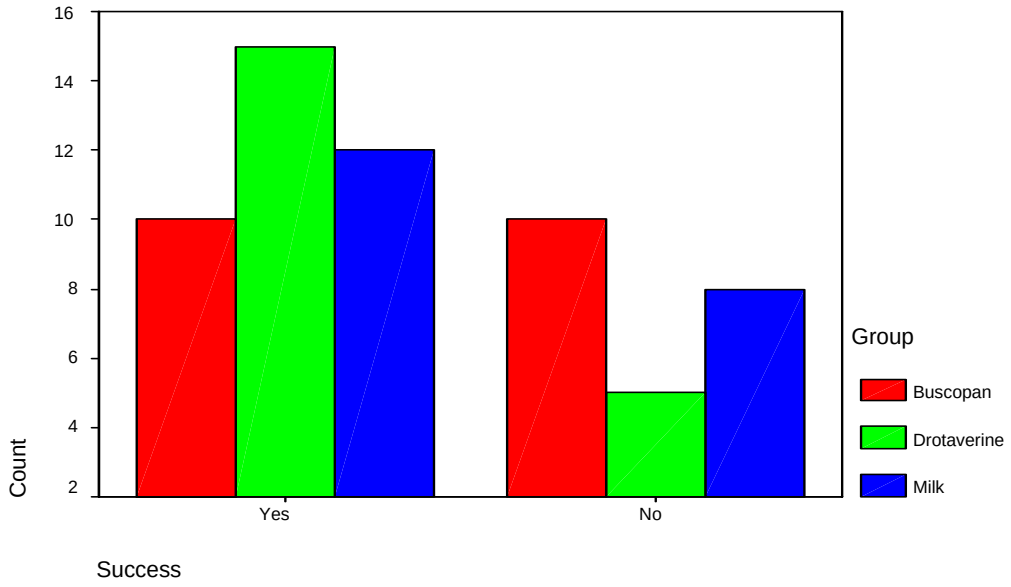
The "p" value is 0.567. Hence there is **no significant difference in duodenal motility** during the procedure between the three groups.

CANNULATION SUCCESS:

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	2.679(a)	2	0.262
Likelihood Ratio	2.741	2	0.254
Linear-by-Linear Association	.416	1	0.519
N of Valid Cases	60		

a 0 cells (.0%) have expected count less than 5. The minimum expected count is 7.67.



The “p” value by Pearson Chi-Square is 0.262. Hence there is **no significant difference in successful cannulation** between the three groups.

CANNULATION TIME (minutes):

	N	Mean	Std. Deviation	95% Confidence Interval for Mean		Min	Max
				Lower Bound	Upper Bound		
Hyoscine	10	4.00	1.764	2.74	5.26	2	7
Drotaverine	15	4.67	2.769	3.13	6.20	1	12
Milk	12	5.00	1.651	3.95	6.05	3	8

ANOVA

	Sig.
Between Groups	0.568

The “p” value is 0.568. Hence there is **no significant difference in cannulation time** between the three groups.

ADVERSE EFFECTS OF DRUGS USED IN COMPARISON WITH FATTY MEAL:

PULSE RATE (Pr/min):

		N	Mean	Std. Deviation	95% Confidence Interval for Mean		Min.	Max.
Pr-Difference					Lower Bound	Upper Bound		
	Hyoscine	20	51.55	12.874	45.52	57.58	34	83
	Drotaverine	20	24.20	8.433	20.25	28.15	12	38
	Milk	20	24.40	8.834	20.27	28.53	8	41

ANOVA

	Sig.
Pr-Difference	0.000

The “p” value is 0.000. Hence there is **significant difference in pulse rate variability** during the procedure between the three groups, which is greater with the Hyoscine-N-butyl bromide group.

BLOOD PRESSURE (mm of Hg):

		N	Mean	Std. Deviation	95% Confidence Interval for Mean		Min.	Max.
					Lower Bound	Upper Bound		
Diff (Sys)	Hyoscine	20	18.30	7.713	14.69	21.91	0	30
	Drotaverine	20	9.00	5.712	6.33	11.67	4	30
	Milk	20	10.40	4.661	8.22	12.58	4	20
Diff (Dia)	Hyoscine	20	15.70	9.091	11.45	19.95	4	34
	Drotaverine	20	8.70	5.630	6.07	11.33	0	20
	Milk	20	8.60	3.315	7.05	10.15	4	16

ANOVA

	Sig.
Diff (Sys)	0.000
Diff (Dia)	0.001

The “p” value for difference in systolic and diastolic blood pressure during the procedure is 0.000 and 0.001 respectively. Hence there is **significant difference in blood pressure variability** between the three groups, which is greater with the Hyoscine-N-butyl bromide group.

In Heart Disease Patients-

CHARACTERISTICS	HYOSCINE-N-BUTYL BROMIDE	DROTAVERINE	LIQUID FATTY MEAL
PULSE RATE VARIABILITY/MIN	63.8	20	27
BP VARIABILITY SYS/DIA mm of Hg	18/11.2	7.3/5.6	13.2/9.2

DISCUSSION

DISCUSSION

ERCP is one of the procedures performed by gastrointestinal endoscopists, which requires adequate expertise to minimize the complication rates. The morbidity and mortality varies between 5-10% and 0.1-1%, respectively[60-64]. It basically depends on the indications, endoscopic technique adopted and cannulation time.

Inhibition of intestinal motility is a pre-requisite for patients undergoing ERCP, which is generally achieved by usage of glucagon[65]. Hyoscine-N- butyl bromide is a cheap and effective alternative to glucagon, due to its easy availability in many centres[66]. But Hyoscine-N-butyl bromide has its adverse effects due to its anticholinergic effects.

Drotaverine hydrochloride is a papaverine analogue which causes smooth muscle relaxation by inhibiting phosphodiesterase IV and a mild calcium channel-blocker. It is a non-anticholinergic compound. Adverse effects like palpitation, hypotension, nausea and vertigo are milder. It can be an alternate to intravenous Hyoscine-N-butyl bromide during ERCP, as an antimotility agent. It has been proved to be a better alternative as antimotility agent before ERCP[67].

Fatty meal has been proposed to cause gall bladder contraction and enhance the flow of bile through the ampulla, easing the visualization of ampulla on a side viewing duodenoscope. It has also been proposed to relax the sphincter of oddi at the ampulla and ease in cannulation success. It has also been proposed to release Neurotensin, a polypeptide hormone from the neurons and cells of the ileal mucosa and inhibit gastrointestinal motility. Giving oil orally before ERCP leads to opening of papillary orifice without any difference in the rates of successful cannulation, time for cannulation and fluoroscopy times has been already proved[68]. In this current study we have studied the effect of 200ml of milk, given one hour before ERCP.

In the present series 60 patients admitted for ERCP at the Department of Medical Gastroenterology, Madras Medical College and Rajiv Gandhi Government General Hospital, Chennai-03, during the period of September 2013 to June 2014 were analyzed with 20 patients randomly allocated in each group.

In the present study, the Hyoscine-N-butyl bromide group with 20 patients comprised of 12 male and 8 female patients. The maximum numbers were in the 41-50 years age group. There were 14 biliary cases and 6 pancreatic cases, with a successful cannulation rate of 42.85% in biliary cases and 66.66% successful cannulation for pancreatic cases. The overall successful cannulation rate was 50%. The maximum numbers of cases were with common bile duct stricture. B F Hannigan et al, has showed that Hyoscine-N-butyl bromide 40 mg and glucagon 1mg given intravenously were equally effective given 1.8 and 1.65 times during the procedure for 50 patients in decreasing the duodenal motility during ERCP[66]. Our study group patients required only 20 mg of Hyoscine-N-butyl bromide. But the data on its effect on cannulation of the ducts are lacking, which has also been analyzed in this present study.

In the Drotaverine group 20 patients comprised of 13 male and 7 female patients were present. The maximum numbers were in the 41-50 years age group. There were 16 biliary and 4 pancreatic cases with a successful cannulation rate of 68.75% in biliary cases and 100% successful cannulation for pancreatic cases. The overall successful cannulation rate was 75%. The maximum numbers of cases were with common bile duct stones, resulting in better cannulation rates. Wang Peng et al, has shown that Drotaverine 40 mg IV could be used as a suitable alternative to conventionally used Hyoscine-N-butyl bromide during ERCP with similar effects on duodenal motility and cannulation success in 650 patients but has also noted a higher incidence of tachycardia with Hyoscine-N-butyl bromide [67].

	Wang Peng et al			Current study		
	Hyoscine	Drotaverine	"p" value	Hyoscine	Drotaverine	"p" value
Duodenal motility difference	1.17 ±0. 82	1.13 ± 0.89	0. 705	0.4±0.883	0.7±1.174	0.572
Cannulation Success	90. 9%	91.8%	0. 672	50%	75%	0.262

A similar result as to that of Wang Peng et al has been documented by this present study on its effect on duodenal motility and cannulation success rates. This study has also documented a higher variation in blood pressure during the ERCP procedure and also the time taken to achieve cannulation.

In the fatty meal group 20 patients comprised of 15 male and 5 female patients were present. The maximum numbers were in the age group of 51-60 years. There were 14 biliary and 6 pancreatic cases with a successful cannulation rate of 71.42% in biliary cases and 33.33% successful cannulation for pancreatic cases. The overall successful cannulation rate was 60%. The maximum numbers of cases were with common bile duct stones. Mihir S. Wagh et al, has showed that usage of edible oil made the biliary channel to open and bile was seen flowing, but without any statistically significant difference in cannulation rates in 86 patients with edible oil compared with 103 patients as control[68].

	Cannulation time in minutes	"p" value	Cannulation Success	"p" value
Mihir S. Wagh et al with Oil	1.9	0.10	93%	0.77
Current study with Milk	5	0.568	60%	0.262

A similar result as to that of Mihir S. Wagh et al has been documented by this present study on its effect on cannulation time and cannulation success rates. This study has also documented the effect of fatty meal in inhibiting the duodenal contractions during the ERCP procedure to ease cannulation and also extended parameters like variation in pulse rate and blood pressure in comparison to the conventionally used Hyoscine-N-butyl bromide and Drotaverine.

In the present series, the average baseline duodenal motility rates in the Hyoscine-N-butyl bromide group, Drotaverine group and fatty meal group were 14.1/minute, 13.75/minute and 13.95/minute respectively. During the procedure, after administration of corresponding agents as per the protocol, the average duodenal motility rates were 0.4/minute in the Hyoscine-N-butyl bromide group, 0.7/minute in the Drotaverine group and 0.35/minute in the fatty meal group. There was a significant decrement of duodenal motility in the fatty meal group comparable to the Hyoscine-N-butyl bromide and Drotaverine groups. This proves that fatty meal is a safe regular dietary measure to aid in ERCP without usage of drugs, thereby avoiding possible adverse effects of drugs. The ampulla was also easily identifiable with fatty meal due to bile flow and staining of the mucosa at the site.

In the present series, the average cannulation time in the Hyoscine-N-butyl bromide group, Drotaverine group and fatty meal group were 4 minutes, 4.66 minutes and 5 minutes respectively.

In the present study, the adverse effects of drugs due to their inherent properties of alteration in pulse rate and blood pressure were recorded. The average pulse rate variation from baseline, during the procedure was 51.55/minute in the Hyoscine-N-butyl bromide group and 24.2/minute in the Drotaverine group. Whereas, in the fatty meal group, the average pulse rate variation was 24.4/minute. This is comparable to that of Drotaverine group. This implies Drotaverine has a lower pulse rate variability compared to that of Hyoscine-N-butyl bromide and is relatively safe.

The average blood pressure variation, both systolic and diastolic from baseline, during the procedure was 18.3/15.7 mm of Hg in the Hyoscine-N-butyl bromide group and 9/8.7 mm of Hg in the Drotaverine group. In the fatty meal group, the average variation in blood pressure was 10.4/8.6 mm of Hg. This data has not been reported by the previous studies.

Other finding in this study is that, the average pulse rate variability in patients with heart disease in Hyoscine-N-butyl bromide group was 63.8/minute, in Drotaverine group was 20/minute compared to 27/minute in fatty meal group. This could be a significant increase in pulse rate and heart rate in patients with underlying ischemic heart disease, causing an inducible ischemia in the Hyoscine-N-butyl bromide group.

The average blood pressure variability in Hyoscine-N-butyl bromide group in both systolic and diastolic pressures were 18/11.2 mm of Hg, in Drotaverine group was 7.3/5.6 mm of Hg compared to 13.2/9.2 mm of Hg in the fatty meal group.

SUMMARY

SUMMARY

1) The average duodenal motility during the procedure with Hyoscine-N-butyl bromide was 0.4/minute, with Drotaverine was 0.7/minute and with fatty meal was 0.35/minute.
2) The average time for cannulation was 4 minutes with Hyoscine-N-butyl bromide, 4.5 minutes with Drotaverine and 5 minutes with fatty meal.
3) The success rates of cannulation were 50% with Hyoscine-N-butyl bromide, 75% with Drotaverine and 60% with fatty meal.
4) Ampulla was easily identifiable with fatty meal by means of bile staining.
5) Increase in pulse rate and blood pressure during the procedure was higher with the use of Hyoscine-N-butyl bromide-N-butyl bromide.
6) The difference in duodenal motility, cannulation time and success of the procedure did not show a statistically significant “p” value.
7) Whereas, the statistical analysis showed a significant “p” value for change in pulse rate and blood pressure variation during the procedure, which was higher with Hyoscine-N-butyl bromide group.

CONCLUSION

CONCLUSION

In the current study fatty meal is not inferior to the conventionally used Hyoscine-N-butyl bromide or its alternate Drotaverine for its anti-motility effect on the duodenum during ERCP. The cannulation time is no different within the groups. The identification of ampulla was easier with the fatty meal group. There is a possibility of higher increase in pulse rate and blood pressure in patients with ischemic heart disease with the use of Hyoscine-N-butyl bromide.

Further larger randomized trials are required to confirm the efficacy of fatty meal in ERCP.

BIBLIOGRAPHY

BIBLIOGRAPHY

1) McCune WS, Shorb PE, Moscovitz H. Endoscopic cannulation of the ampulla of vater: a preliminary report. Ann Surg. 1968;167:752-756
2) Leung JW, Chung RS. Training in ERCP. Gastrointest Endosc 1992;38:517-9
3) Al-Kawas FH. Biliary access during endoscopic retrograde cholangiopancreatography: how to precut and a word of caution!. J Gastroenterol Hepatol. 2005;20:805-806
4) Wehbi M, Obidden M, Shaukat A, Cai Q. Deep cannulation of the common bile duct - How challenging is it?. Gastrointest Endosc. 2004;59:186
5) Freeman ML , DiSario JA , Nelson DB , et al. **Risk factors for post-ERCP pancreatitis: a prospective, multicenter study .** *Gastrointest Endosc* . 2001;54:425–434
6) Badalov N , Tenner S , Baillie J . **The prevention, recognition and treatment of post-ERCP pancreatitis .** *JOP* . 2009;10:88–97
7) Freeman ML , Guda NM . **ERCP cannulation: a review of reported techniques .** *Gastrointest Endosc* . 2005;61:112–125
8) Abdel Aziz AM , Lehman GA . **Pancreatitis after endoscopic retrograde cholangio-pancreatography .** *World J Gastroenterol* . 2007;13:2655–2668

9) Barrie M , Klein SD , Brown CA , et al. **Endoscopic retrograde cholangiopancreatography after a liquid fatty meal: effect on deep common bile duct cannulation time .** *Endoscopy* . 2006;38:241–248

10) Fayad LM, Kowalski T, Mitchell DG. MR cholangiopancreatography: evaluation of common pancreatic diseases. Rad Clin N Am 2003;41:97-114

11) Motohara T, Semelka RC, Bader T. MR cholangiopancretography. Rad Clin N Am 2003;41:89-96

12) Masunari H, Shimada H, Endo I, et al: Surgical anatomy of hepatic hilum with special reference of the plate system and extrahepatic duct. J Gastrointest Surg 2008; 12:1047-53.

13) Saxena R, Theise N: Canals of Hering: Recent insights and current knowledge. Semin Liver Dis 2004; 24:43-8

14) Adkins Jr RB, Chapman WC, Reddy VS: Embryology, anatomy, and surgical applications of the extrahepatic biliary system. Surg Clin North Am 2000; 80:363-79

15) Jones A, Spring-Mills E: The liver and gallbladder. In: Weiss L, ed. Modern concepts of gastrointestinal histology, New York: Elsevier; 1983:738

16) Avisse C, Flament JB, Delattre JF: Ampulla of Vater. Anatomic, embryologic, and surgical aspects. Surg Clin North Am 2000; 80:201-12.

17) Kimura K, Ohto M, Saisho H, et al: Association of gallbladder carcinoma and anomalous pancreaticobiliary ductal union. Gastroenterology 1985; 89:1258

18) Misra SP, Gulati P, Thorat VK, et al: Pancreaticobiliary ductal union in biliary disease: An endoscopic retrograde cholangiopancreatography study. Gastroenterology 1989; 96:907.

19) Artifon EL, Sakai P, Cunha JE, Halwan B, Ishioka S, Kumar A. Guidewire cannulation reduces risk of post-ERCP pancreatitis and facilitates bile duct cannulation. Am J Gastroenterol. 2007;102:2147-2153

20) Rossos PG, Kortan P, Haber G. Selective common bile duct cannulation can be simplified by the use of a standard papillotome. Gastrointest Endosc. 1993;39:67-69

21) Cortas GA, Mehta SN, Abraham NS, Barkun AN. Selective cannulation of the common bile duct: a prospective randomized trial comparing standard catheters with sphincterotomes. Gastrointest Endosc. 1999;50:775-779

22) Schwacha H, Allgaier HP, Deibert P, Olschewski M, Allgaier U, Blum HE. A sphincterotome-based technique for selective transpapillary common bile duct cannulation. Gastrointest Endosc. 2000;52:387-391

23) Carr-Locke DL. Biliary access during endoscopic retrograde cholangiopancreatography. Can J Gastroenterol. 2004;18:251-254

24) Gullichsen R, Lavonius M, Laine S, Grönroos J. Needle-knife assisted ERCP. Surg Endosc. 2005;19:1243-1245

25) Lella F, Bagnolo F, Colombo E, Bonassi U. A simple way of avoiding post-ERCP pancreatitis. Gastrointest Endosc. 2004;59:830-834

26) Lee TH, Park do H, Park JY, Kim EO, Lee YS, Park JH, Lee SH, Chung IK, Kim HS, Park SH. Can wire-guided cannulation prevent post-ERCP pancreatitis? A prospective randomized trial. Gastrointest Endosc. 2009;69:444-449

27) Bailey AA, Bourke MJ, Williams SJ, Walsh PR, Murray MA, Lee EY, Kwan V, Lynch PM. A prospective randomized trial of cannulation technique in ERCP: effects on technical success and post-ERCP pancreatitis. Endoscopy. 2008;40:296-301

28) Katsinelos P, Paroutoglou G, Kountouras J, Chatzimavroudis G, Zavos C, Pilpilidis I, Tzelas G, Tzovaras G. A comparative study of standard ERCP catheter and hydrophilic guide wire in the selective cannulation of the common bile duct. Endoscopy. 2008;40:302-307

29) Bruins Slot W, Schoeman MN, Disario JA, Wolters F, Tytgat GN, Huibregtse K. Needle-knife sphincterotomy as a precut procedure: a retrospective evaluation of efficacy and complications. Endoscopy. 1996;28:334-339

30) Binmoeller KF, Seifert H, Gerke H, Seitz U, Portis M, Soehendra N. Papillary roof incision using the Erlangen-type pre-cut papillotome to achieve selective bile duct cannulation. Gastrointest Endosc. 1996;44:689-695

31) Huibregtse K, Katon RM, Tytgat GN. Precut papillotomy via fine-needle knife papillotome: a safe and effective technique. Gastrointest Endosc. 1986;32:403-405

32) Cotton PB. Precut papillotomy--a risky technique for experts only. Gastrointest Endosc. 1989;35:578-579

33) Mavrogiannis C, Liatsos C, Romanos A, Petoumenos C, Nakos A, Karvountzis G. Needle-knife fistulotomy versus needle-knife precut papillotomy for the treatment of common bile duct stones. Gastrointest Endosc. 1999;50:334-339

34) Siddiqui AR, Niaz SK. Needle knife papillotomy for cannulating difficult papilla; two years experience. J Pak Med Assoc. 2008;58:195-197

35) Freeman ML, Nelson DB, Sherman S, Haber GB, Herman ME, Dorsher PJ, Moore JP, Fennerty MB, Ryan ME, Shaw MJ. Complications of endoscopic biliary sphincterotomy. N Engl J Med. 1996;335:909-918

36) Cennamo V, Fuccio L, Zagari RM, Eusebi LH, Ceroni L, Laterza L, Fabbri C, Bazzoli F. Can early precut implementation reduce endoscopic retrograde cholangiopancreatography-related complication risk? Meta-analysis of randomized controlled trials. Endoscopy. 2010

37) Manes G, Di Giorgio P, Repici A, Macarri G, Ardizzone S, Porro GB. An analysis of the factors associated with the development of complications in patients undergoing precut sphincterotomy: a prospective, controlled, randomized, multicenter study. Am J Gastroenterol. 2009;104:2412-2417

38) Bailey AA, Bourke MJ, Kaffes AJ, Byth K, Lee EY, Williams SJ. Needle-knife sphincterotomy: factors predicting its use and the relationship with post-ERCP pancreatitis (with video). Gastrointest Endosc. 2010;71:266-271

39) Vandervoort J, Carr-Locke DL. Needle-knife access papillotomy: an unfairly maligned technique?. Endoscopy. 1996;28:365-366

40) Caletti GC, Vandelli A, Bolondi L, Fontana G, Labò G. Endoscopic retrograde cholangiography (ERC) through artificial endoscopic choledocho-duodenal fistula. Endoscopy. 1978;10:203-206

41) Artifon ELA, Sakai P, Ishioka S, Hondo FY, Raju GS. Suprapapillary puncture of the common bile duct for selective biliary access: a novel technique (with videos). Gastrointestinal Endoscopy. 2007;65:124-131

42) Donnellan F, Zeb F, Courtney G, Aftab AR. Suprapapillary needleknife fistulotomy: a safe and effective method for accessing the biliary system. Surg Endosc. 2010

43) Dumonceau JM, Devière J, Cremer M. A new method of achieving deep cannulation of the common bile duct during endoscopic retrograde cholangiopancreatography. Endoscopy. 1998;30:S80

44) Gotoh Y, Tamada K, Tomiyama T, Wada S, Ohashi A, Satoh Y, Higashizawa T, Miyata T, Ido K, Sugano K. A new method for deep cannulation of the bile duct by straightening the pancreatic duct. Gastrointest Endosc. 2001;53:820-822

45) Maeda S, Hayashi H, Hosokawa O, Dohden K, Hattori M, Morita M, Kidani E, Ibe N, Tatsumi S. Prospective randomized pilot trial of selective biliary cannulation using pancreatic guide-wire placement. Endoscopy. 2003;35:721-724

46) Ito K, Fujita N, Noda Y, Kobayashi G, Obana T, Horaguchi J, Takasawa O, Koshita S, Kanno Y. Pancreatic guidewire placement for achieving selective biliary cannulation during endoscopic retrograde cholangio-pancreatography. World J Gastroenterol. 2008;14:5595-5600

47) Fujita N, Noda Y, Kobayashi G, Kimura K, Yago A. ERCP for intradiverticular papilla: two-devices-in-one-channel method. Endoscopic Retrograde Cholangiopancreatography. Gastrointest Endosc. 1998;48:517-520

48) Kahaleh M, Tokar J, Mullick T, Bickston SJ, Yeaton P. Prospective evaluation of pancreatic sphincterotomy as a precut technique for biliary cannulation. Clin Gastroenterol Hepatol. 2004;2:971-977

49) Wang P, Zhang W, Liu F, Li ZS, Ren X, Fan ZN, Zhang X, Lu NH, Sun WS, Shi RH. Success and complication rates of two precut techniques, transpancreatic sphincterotomy and needle-knife sphincterotomy for bile duct cannulation. J Gastrointest Surg. 2010;14:697-704

50) Fogel EL, Sherman S, Lehman GA. Increased selective biliary cannulation rates in the setting of periampullary diverticula: main pancreatic duct stent placement followed by pre-cut biliary sphincterotomy. Gastrointest Endosc. 1998;47:396-400

51) Devereaux BM, Fein S, Purich E, Trout JR, Lehman GA, Fogel EL, Phillips S, Etemad R, Jowell P, Toskes PP. A new synthetic porcine secretin for facilitation of cannulation of the dorsal pancreatic duct at ERCP in patients with pancreas divisum: a

multicenter, randomized, double-blind comparative study. Gastrointest Endosc. 2003;57:643-647

52) Park SH, de Bellis M, McHenry L, Fogel EL, Lazzell L, Bucksot L, Sherman S, Lehman GA. Use of methylene blue to identify the minor papilla or its orifice in patients with pancreas divisum. Gastrointest Endosc. 2003;57:358-363

53) Kilander AF, Hanssen LE, Gillberg RE. Secretin release in coeliac disease. Plasma secretin concentration and bicarbonate output to the duodenum after intraduodenal acid infusion in coeliac patients before and after treatment. Scand J Gastroenterol. 1983;18:765-769

54) Cai Q, Keilin S, Obideen K, Li Y. Intraduodenal hydrochloric acid infusion for facilitation of cannulation of the dorsal pancreatic duct at ERCP in patients with pancreas divisum - a preliminary study. Am J Gastroenterol. 2010

55) Weston AP. Sincalide: a cholecystokinin agonist as an aid in endoscopic retrograde cholangiopancreatography--a prospective assessment. J Clin Gastroenterol. 1997;24:227-230

56) Thompson JN, Gupta S, Murray JK, Clements WG, Blumgart LH. A randomized double-blind trial of cholecystokinin during ERCP. Endoscopy. 1986;18:251

57) Wehrmann T, Schmitt T, Stergiou N, Caspary WF, Seifert H. Topical application of nitrates onto the papilla of Vater: manometric and clinical results. Endoscopy. 2001;33:323-328

58) Talwar A, Dare C, Pain J. Does topical GTN on the sphincter of Oddi facilitate ERCP? A double-blind randomized control trial. Surg Endosc. 2005;19:902-904

59) Barrie M, Klein SD, Brown CA, Edge MD, Affronti JA, Cai Q. Endoscopic retrograde cholangiopancreatography after a liquid fatty meal: effect on deep common bile duct cannulation time. Endoscopy. 2006;38:241-248

60) Schutz SM, Abbott RM. Grading ERCPs by degree of difficulty: a new concept to produce more meaningful outcome data. Gastrointest Endosc 2000;51:535-9

61) Sultan S, Baillie J. What are the predictors of post-ERCP pancreatitis, and how useful are they? JOP 2002;3:188-94

62) Standards of Practice Committee. Complications of ECP. Gastrointest Endosc 2003;57:633-8

63) Vandervoort J, Soetikno RM, Tham TC, et al. Risk factors for complications after performance of ERCP. Gastrointest Endosc 2002;56:652-6

64) Baillie J. Predicting and preventing post-ERCP pancreatitis. Curr Gastro Rep 2002; 4:112-9

65) Lahoti S et al. A prospective, double-blind trial of L-hyoscyamine versus glucagon for the inhibition of small intestinal motility during ERCP: Gastrointest Endosc. 1997 Aug;46(2):139-42

66) B F Hannigan et al. Buscopan or glucagon for endoscopic cannulation of ampulla of vater?

67) Wang Peng et al, Pretreatment with Drotaverine Hydrochloride before endoscopic retrograde cholangiopanc reatogra-phy: a prospective multicenter randomized controlled trial: Chinese Journal of Digestive Endoscopy 2009; 26(8) : 397-401

68) Mihir S. Wagh et al, Oral administration of edible oil before ERCP: effect on selective biliary cannulation: **Gastrointestinal Endoscopy** Volume 77, Issue 1 , Pages 55-61, January 2013.

ANNEXURES

PROFORMA

PROFORMA

Comparative study of Fatty meal versus Drotaverine Hydrochloride versus Hyoscine-N-butylbromide for Duodenal Antimotility and ease of cannulation During Endoscopic Retrograde Cholangiopancreatography (ERCP)

NAME: AGE: SEX: IP/GE.NO:

MILK ALLERGY: Y/N GLAUCOMA: Y/N OBSTRUCTIVE UROPATHY: Y/N

BILLROTH II GASTRECTOMY: Y/N SERUM CREATININE:

PREGNANT OR BREASTFEEDING: Y/N

ECG:

CARDIAC STATUS: DIAGNOSIS:

GROUP: FATTY MEAL / BUSCOPAN / DROTAVERINE

DOSE:

BASELINE:

PR: /MT BP: mmHg

DURING PROCEDURE: DUODENAL MOTILITY (BASE):

PR: /MT BP: mmHg

Duodenal motility grade:

NIL	< 5/MT	5-10/MT	11-15/MT	CONTINUOUS

Cannulation success: YES / NO

Cannulation Time:

ERCP Complications:

Drug adverse effects:

சுய ஒப்புதல் படிவம்

ஆய்வு செய்யப்படும் தலைப்பு

குடல்குழாய் உள்நோக்கல் பிற்போக்கு பித்தம் மற்றும் கணையக்குழாய் ஆய்வு வரைவு(ERCP) போது சிறுகுடல் மேற்பகுதிக்குரிய இயக்க எதிர்செயலி மற்றும் புனல் உட்புகல் எளிதாக்க ஹயோசின்ப்யூடைல்ப்ரோமைட் எதிராக திரொதவெறின்ஹைட்ரோகுளோரைடு எதிராக கொழுப்பு உணவு ஒப்பீட்டு ஆய்வு

ஆராய்ச்சி நிலையம்: சென்னை மருத்துவக்கல்லூரி மற்றும் ராஜிவ்காந்தி அரசு பொது மருத்துவமனை, சென்னை-600003

பங்கு பெறுபவரின் பெயர்:

பங்கு பெறுபவரின் எண்:

பங்கு பெறுபவர் இதனை(√) குறிக்கவும்.

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும், அதற்கான தகுந்த விளக்கங்களை பெறவும் வாய்ப்பளிக்கப்பட்டது.

நான் இவ்வாய்வில் தன்னிச்சையாகத்தான் பங்கேற்கிறேன். எந்த காரணத்தினாலும் எந்த கட்டத்திலும் எந்த சட்டசிக்கலுக்கும் உட்ப்டாமல் நான் இவ்வாய்வில் இருந்து விலகிக்கொள்ளலாம்
என்றும் அறிந்து கொண்டேன்.

இந்த ஆய்வு சம்பந்தமாகவோ, இதை சார்ந்த மேல் ஆய்வு மேற்கொள்ளும் போதும் இந்த ஆய்வில்
பங்கு பெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என்னுடைய அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். நான் ஆய்வில் இருந்து விலகிக்கொண்டாலும் இது
பொருந்தும் என அறிகிறேன்.

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான தகவல்களையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக்கொள்ளவும் அதைபிரசுரிக்கவும் என் முழுமனதுடன் சம்மதிக்கிறேன்.

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன். எனக்கு கொடுக்கப்பட்ட அறிவுரைகளின் படி

நடந்து கொள்வதுடன், இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என உறுதியாளிக்கிறேன்.

இந்த ஆய்வில் எனக்கு ரத்தம், சிறுநீர், ஊடுகதிர்படம், இதய மின்துடிப்பு வரைவு மற்றும் குடற்குழாய் உள்நோக்கல் பரிசோதனை செய்து கொள்ள நான் முழு மனதுடன் சம்மதிக்கிறேன்..

பங்கேற்பவரின் கையொப்பம்: இடம்: தேதி:

பெருவிரல் ரேகை:

பங்கேற்பவரின் பெயர் மற்றும் முகவரி:

ஆய்வாளரின் கையொப்பம்: இடம்: தேதி:

ஆய்வாளரின் பெயர்:

நோயாளியின் உறவினர்/ காப்பாளர் கையொப்பம்: இடம்: தேதி:

INFORMED CONSENT FORM

Title of the Study:

Comparative study of Fatty meal versus Drotaverine Hydrochloride versus Hyoscine-N-butylbromide for duodenal anti-motility and ease of cannulation during Endoscopic Retrograde Cholangiopancreatography (ERCP)

Name of the Participant:

_____

Name of the Investigator: Dr. S. Vadivel Kumaran

Name of the Institution : Madras Medical College.

Documentation of the informed consent

I _____ have read the information in this form (or it has been read to me). I was free to ask any questions and they have been answered. I hereby give my consent to be included as a participant in

The Comparative study of Fatty meal versus Drotaverine Hydrochloride versus Hyoscine-N-butylbromide for duodenal anti-

motility and ease of cannulation during Endoscopic Retrograde Cholangiopancreatography (ERCP)

1. I have read and understood this consent form and the information provided to me.
2. I have had the consent document explained to me.
3. I have been explained about the nature of the study.
4. I have been explained about my rights and responsibilities by the investigator.

Name and signature / thump impression of the participant

Name _____ Signature _____ Date____

Name and signature of impartial witness (required for illiterate patients):

Name _____ Signature _____ Date____

Address and contact number of the impartial witness:

Name and signature of the investigator or his representative obtaining consent:

ஆய்வு தகவல் தாள்

சென்னை மருத்துவக்கல்லூரி மற்றும் ராஜிவ்காந்தி அரசு பொது மருத்துவமனை க்கு வரும் நோயாளிகளில், குடற்குழாய் உள்நோக்கல் பிற்போக்கு பித்தம் மற்றும் கணையக்குழாய் வரைவு (ERCP) ஆய்வு சிகிச்சைக்கு வரும் நோயாளிகள் குறித்த ஆய்வு இங்கு நடைபெற்று வருகிறது.

நீங்கலும் இந்த ஆராய்ச்சியில் பங்கேற்க, நாங்கள் விரும்புகிறோம். இந்த ஆராய்ச்சியில் உங்களை பங்கேற்க் வைத்து அதன் தகவல்களை ஆராய்வோம். அதனால் தங்கள் நோயின் ஆய்வரிக்கையோ ,சிகிச்சையோ பாதிக்கப்படாது என்பதை தெரிவித்திக்கொள்கிறோம்.

முடிவுகளை அல்லது கருத்துக்களை வெளியிடும்போதோ அல்லது ஆராய்ச்சியின்போதோ தங்களின் பெயரையோ அல்லது ஆடையாளங்களையோ வெளியிட மாட்டோம் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

இந்த ஆராய்ச்சியில் பங்கேற்பது தங்களுடைய விருப்பத்தின் பேரில் தான் இருக்கிறது மேலும் நீங்கள் எந்நேரமும் இந்த ஆராய்ச்சியிலிருந்து வெளியேறலாம் என்பதையும் தெரிவித்துக்கொள்கிறோம்.

ஆராய்ச்சியாளர் கையொப்பம் பங்கேற்பவரின் கையொப்பம்

நோயாளியின் உறவினர்/ காப்பாளர் கையொப்பம்

Information sheet

We are conducting a study on "**Comparative study of Fatty meal versus Drotaverine Hydrochloride versus Hyoscine-N-butylbromide for duodenal anti-motility and ease of cannulation during Endoscopic Retrograde Cholangiopancreatography (ERCP)**" at The Department of Medical Gastroenterology, Rajiv Gandhi Govt. General Hospital, Chennai. The purpose of the study is to compare the efficacy of the conventionally used Hyosine to Drotaverine and fatty meal, in Endoscopic Retrograde Cholangiopancreatography (ERCP)

The privacy of the patients in this research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time. Your decision will not result in any loss of benefits to which you are otherwise entitled.

The results of the study may be intimated to you at the end of the study period or during the study if anything is found abnormal. This may aid in the management or treatment.

Signature of Investigator Signature of participant

Date:

FATTY MEAL

NAME	I.P.NO	AGE	SEX	DIAGNOSIS	MILK ALLERGY	GLAUCOMA	OBST. UROPATHY	BIL II GASTRECTOMY	PREG/ BR. FEED	SR. CREAT	ECG	ECHO	PR-BASELINE	PR-PROCEDURE	BP-BASELINE - Sys	BP-BASELINE - Dia	BP-PROCEDURE - Sys	BP-PROCEDURE - Dia	DM-BASELINE	DM-PROCEDURE	SUCCESS	CANNULATION TIME	DRUG ADVERSE EFFECT
BHAVANI	17815	30	FEMALE	BILE LEAK	N	N	N	N	N	0.7	SINUS TACHY	66	106	140	116	70	128	86	14	1	N		NIL
VANAMALA	1214/14	48	FEMALE	CBD STONE	N	N	N	N	N	1	AW-ISCHEMIA	58	78	96	110	70	118	78	14	0	Y	4	NIL
VALLI	25380	30	FEMALE	LIVER ABSCESS	N	N	N	N	N	0.9	SINUS TACHY	68	86	94	110	70	126	76	12	0	Y	6	NIL
MOHANA	6869/13	40	FEMALE	CBD STONE	N	N	N	N	N	1	WNL	66	72	88	110	70	116	76	13	0	Y	5	NIL
AKILANDAM	4724/13	52	FEMALE	CBD STONE	N	N	N	N	N	1.6	IW-ISCHEMIA	62	96	128	120	70	132	76	14	0	Y	6	NIL
NARASIMMAN	15281	70	MALE	CBD STONE/GB STONE	N	N	Y	N	N	0.9	IW-ISCHEMIA	56	90	131	110	70	126	86	13	0	N		NIL
POTRAMARAI	1250/14	27	MALE	CHRONIC PANCREATITIS /PSEUDOCYST	N	N	N	N	N	0.6	SINUS TACHY	62	88	120	120	86	130	90	18	1	N		NIL
THIRUNAVUKKARASU	421	37	MALE	RAP/ PD STRICTURE	N	N	N	N	N	0.8	WNL	60	90	118	110	70	116	80	13	0	Y	3	NIL
LAZER	4669	60	MALE	CHRONIC PANCREATITIS / PSEUDOCYST	N	N	N	N	N	1.1	WNL	58	74	90	110	70	120	80	14	0	N		NIL
THIRUVARUTSELVAN	4637/13	31	MALE	DISTAL CBD STRICTURE	N	N	N	N	N	0.8	WNL	72	76	100	114	70	120	76	12	1	Y	6	NIL
RAMADOSS	18283	52	MALE	DISTAL CBD STRICTURE	N	N	N	N	N	1	WNL	55	76	92	110	72	130	84	15	0	N		NIL
RAJA	20855	54	MALE	DISTAL CCA	N	N	N	N	N	0.8	WNL	60	92	118	116	76	128	86	13	0	N		NIL
SELVARAJ	22992	59	MALE	CBD STONE	N	N	N	N	N	1.1	WNL	58	82	98	118	78	130	88	14	0	Y	8	NIL
THANGASAMY	22176	58	MALE	CBD STONE	N	N	N	N	N	0.6	OLD IWMI	56	88	114	110	76	128	84	12	0	Y	5	NIL
KUMAR	22046	46	MALE	CBD STONE	N	N	N	N	N	1.1	AI-ISCHEMIA	60	82	100	114	72	126	80	16	0	Y	7	NIL
RAVI	1179/14	44	MALE	PANCREATIC ASCITES/ PD LEAK	N	N	N	N	N	0.9	WNL	60	98	131	108	68	112	72	15	4	N		NIL
ABDUL NOOR	1192/14	70	MALE	PSEUDOCYST	N	N	N	N	N	0.9	SINUS TACHY	58	88	126	110	70	116	78	12	0	Y	3	NIL
JANAKIRAMAN	3012/13	30	MALE	CHOLANGITIS	N	N	N	N	N	0.6	WNL	66	74	90	110	70	114	76	16	0	Y	4	NIL
MARUDHAN	1174/14	38	MALE	HILAR CCA	N	N	N	N	N	0.8	SINUS TACHY	60	96	124	116	70	128	78	14	0	Y	3	NIL
SHANKAR	25925	32	MALE	PANCREATIC ASCITES/ PD LEAK	N	N	N	N	N	1.2	WNL	66	78	100	108	68	114	78	15	0	N		NIL

DROTAVERINE GROUP

NAME	I.P.NO	AGE	SEX	DIAGNOSIS	MILK ALLERGY	GLAUCOMA	OBST. UROPATHY	BIL II GASTRECTOMY	PREG/BR. FEED	SR. CREAT	ECG	ECHO	PR-BASELINE	PR-PROCEDURE	BP-BASELINE - Sys	BP-BASELINE - Dia	BP-PROCEDURE -Sys	BP-PROCEDURE - Dia	DM-BASELINE	DM-PROCEDURE	SUCCESS	CANNULATION TIME	DRUG ADVERSE EFFECT
LAKSHMI	73129	14	FEMALE	CHOLEDOCHAL CYST	N	N	N	N	N	0.8	WNL	66	76	90	110	70	120	70	13	0	Y	2	NIL
HABIBU NISHA	82918	50	FEMALE	CBD STONE	N	N	N	N	N	0.9	IW ISCHEMIA	58	78	96	140	96	148	96	16	3	N		NIL
KOKILA	92580	35	FEMALE	POST CHOLE BILE LEAK	N	N	N	N	N	0.8	SINUS TACHYCARDIA	58	106	140	106	70	118	88	18	0	Y	12	NIL
VIJAYALAKSHMI	111225	36	FEMALE	CBD STONE	N	N	NN	N	N	1	WNL	60	76	112	110	70	116	74	12	0	N		NIL
NEBISHA FATHIMA	2890	32	FEMALE	CBD STONE	N	N	N	N	Y	0.6	WNL	66	78	90	118	74	126	80	14	2	N		NIL
VANAJA	11269	32	FEMALE	NODULE HEAD OF PANCREAS	N	N	N	N	N	1.2	WNL	62	88	110	108	70	116	80	15	0	Y	3	NIL
VALLI	151815	30	FEMALE	LIVER ABSCESS/CBD STONE	N	N	N	N	N	1.2	WNL	64	80	114	114	70	120	80	12	3	Y	3	NIL
CHANDRASEKAR	80666	43	MALE	CHOLANGIOLYTIC ABSCESS	N	N	N	N	N	1.6	SINUS TACHYCARDIA	60	98	136	106	70	116	86	16	0	Y	4	NIL
PRAKASH	85849	27	MALE	CCP	N	N	N	N	N	0.6	WNL	60	82	108	110	70	126	80	14	0	Y	6	NIL
KIRUBANANDHAN	40713	50	MALE	CBD STONE/ GB STONE	N	N	N	N	N	1	WNL	60	80	92	116	74	120	80	12	0	Y	3	NIL
NATARAJ	89076	62	MALE	HILAR CCA	N	N	N	N	N	1	AW ISCHEMIA	54	72	88	126	84	130	90	15	3	Y	5	NIL
MURUGAIYAN	102553	43	MALE	CBD STONE	N	N	N	N	N	1	WNL	69	80	108	110	70	140	90	14	0	Y	6	NIL
CHELLIAH	99681	52	MALE	DISTAL CBD STRICTURE	N	N	N	N	N	0.6	AI ISCHEMIA	52	82	104	118	90	124	96	12	0	N		NIL
MUTHUSAMY	100491	45	MALE	CA. HEAD OF PANCREAS	N	N	N	N	N	0.9	WNL	58	78	96	110	70	116	86	15	0	Y	8	NIL
SAMBASIVAM	102276	55	MALE	DISTAL CBD STRICTURE	N	N	N	N	N	0.6	LVH	55	70	98	140	100	146	110	11	0	N		NIL
JEYARAJ	115589	42	MALE	PSEUDOCYST OF HEAD OF PANCREAS	N	N	N	N	N	0.9	WNL	60	96	128	124	80	130	70	13	1	Y	6	PEP
MUGUNTHAN	115950	54	MALE	CBD STONE	N	N	N	N	N	2.1	SINUS TACHYCARDIA	58	108	132	100	70	106	72	14	0	Y	2	NIL
DESINGH	3262	63	MALE	HILAR STRICTURE	N	N	N	N	N	0.8	IW ISCHEMIA	56	84	104	140	102	150	96	15	0	Y	4	NIL
GOTHIKAN	9915	75	MALE	HILAR CCA	N	N	N	N	N	1	AI ISCHEMIA	50	86	102	100	70	110	76	9	0	Y	1	NIL
MARUDHAN	151717	43	MALE	HILAR CCA	N	N	N	N	N	0.9	WNL	58	92	126	106	66	114	78	15	2	Y	5	NIL

BUSCOPAN GROUP

NAME	I.P.NO	AGE	SEX	DIAGNOSIS	MILK ALLERGY	GLAUCOMA	OBST. UROPATHY	BIL II GASTRECTOMY	PREG / BR. FEED	SR.CREAT	ECG	ECHO	PR-BASELINE	PR-PROCEDURE	BP-BASELINE - Sys	BP-BASELINE - Dia	BP-PROCEDURE -Sys	BP-PROCEDURE - Dia	DM-BASELINE	DM-PROCEDURE	SUCCESS	CANNULATION TIME	DRUG ADVERSE EFFECT
MALARKODI	121466	52	FEMALE	CCP	N	N	N	N	N	1.4	WNL	63	88	128	108	70	120	80	16	0	N		NIL
KALAISELVI	120073	30	FEMALE	CBD STONE	N	N	N	N	N	0.7	WNL	60	72	116	110	70	116	80	15	0	N		NIL
SONIYA	85597	28	FEMALE	APBU	N	N	N	N	N	0.8	WNL	70	80	128	110	70	128	78	16	0	Y	2	NIL
KARPAGAMANI	110381	72	FEMALE	POST-CHOLE. BILE LEAK	N	N	N	N	N	0.8	IW-ISCHEMIA	48	110	162	100	70	130	78	13	0	Y	4	NIL
JAYA	110802	45	FEMALE	CBD STONE/GB STONE	N	N	N	N	N	1	WNL	60	76	128	110	70	128	96	12	0	Y	4	NIL
KANNIAMMAL	114616	36	FEMALE	BILIARY PANCREATITIS	N	N	N	N	N	1.4	WNL	66	112	166	126	80	140	100	16	0	N		NIL
EKATHAL	108326	58	FEMALE	DISTAL CBD STRICTURE	N	Y	N	N	N	1.3	SINUS TACHY	56	82	148	110	70	132	96	18	2	N		NIL
AMUDHAVALLI	109416	50	FEMALE	EC FISTULA/ PD LEAK	N	N	N	N	N	0.6	IW-ISCHEMIA	58	88	171	108	90	120	96	16	0	Y	3	NIL
DEVARAJ	116899	24	MALE	MID-CBD STRICTURE	N	N	N	N	N	0.6	WNL	66	76	110	110	70	130	96	18	0	N		NIL
MUNUSAMY	115265	32	MALE	RAP/ PSEUDOCYST	N	N	N	N	N	0.8	WNL	62	96	132	108	66	136	100	12	0	Y	6	NIL
MURUGAN	110361	53	MALE	DISTAL CBD STRICTURE	N	N	N	N	N	1.1	WNL	58	76	118	110	70	130	92	13	0	N		NIL
RAHMAN	11540	50	MALE	OBST. JAUNDICE/ HILAR CCA	N	N	N	N	N	1.2	HIGH LAT. WALL ISCHEMI	62	98	140	160	90	160	86	12	2	N		NIL
RAVICHANDRAN	47349	53	MALE	HILAR CCA	N	N	N	N	N	1.6	SINUS TACHY	55	126	170	120	90	140	94	15	1	Y	6	NIL
PERUMAL	86104	45	MALE	OBSTRUCTIVE JAUNDICE/ HILAR CCA	N	N	N	N	N	1.6	WNL	60	72	118	110	70	126	76	12	0	N		NIL
NATARAJ	89076	62	MALE	OBST. JAUNDICE	N	N	N	N	N	0.9	WNL	66	82	128	110	70	136	94	16	0	N		NIL
RAJANI	89015	34	MALE	PSEUDOCYST	N	N	N	N	N	1.2	SINUS TACHY	68	98	146	140	90	150	100	14	0	Y	7	NIL
MOHAMMED MUZAKKAR	50015	38	MALE	INFECTED LIVER CYST	N	N	N	N	N	1	WNL	68	92	144	100	70	120	80	11	0	Y	3	NIL
RAJA	101833	48	MALE	DISTAL CBD STRICTURE	N	N	N	N	N	1.1	WNL	62	76	136	110	70	136	92	12	0	Y	3	NIL
MUTHUKRISHNAN	109911	67	MALE	GB. CA	N	N	N	N	N	0.9	LVH WITH STRAIN	52	92	158	130	90	150	106	12	0	Y	2	NIL
ELUMALAI	114859	64	MALE	DISTAL CBD STRICTURE	N	N	N	N	N	1	AW-ISCHEMIA	48	88	164	112	74	140	96	13	3	N		NIL